

**Prescribing for prevention in primary care:  
exploring patients' views on risk management medicines**

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for the degree of Doctor of Philosophy  
by

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## Declaration

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This thesis is the result of my own work. The material contained within the thesis has not been presented, either wholly or in part, for any other degree or qualification. All use of material from other sources has been properly and fully acknowledged.

## Abstract

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Prevention of disease is a key strategy in the NHS, contributing to cost-effective health care and lower morbidity and mortality through early identification and management of risk factors in large populations. However, effects of increased prescribing, in the form of a growing burden of treatment for patients and challenges associated with polypharmacy, have prompted criticism from medical practitioners as well as scholars from the biomedical and social scientific fields.

Whilst a growing evidence base guides prescribing, factors in the social world also influence how medicines are used. Patients' views on medicines are recognised as important for a good outcome of treatment, but they are not very well known with regards to risk management prescribing and polypharmacy. The research presented in this thesis draws on critical examinations of societal influences on large-scale prescribing, and focuses on cardiovascular (CVD) risk management in primary care. This approach allowed me to explore the use of medicines in a setting where prescribing is common but also involves challenges in terms of the balancing of beneficial and harmful effects for populations and individuals.

General influences on patients' expectations of prescribed medicines were addressed in a review and synthesis of medical and social scientific literature describing beliefs, views and experiences. An update of the national clinical guidance on CVD risk assessment and modification of blood lipids offered an opportunity to review how CVD risk and the benefit and harm from statins were represented in a lay context; UK newspapers. In the empirical part of the research, I explored patients' understanding of their own use of medicines in CVD risk management. My findings produced a thematic structure describing how patients conceptualise a diagnosed CVD risk and make sense of the recommended risk management treatments.

Central influences on patients' views are a simplified representation of CVD risk as a distinct condition with particular consequences for the individual, anticipation of defined effects from medicines, and a personalised understanding of health information which leads to individual responsibility for engaging with risk management. To propose implications of my findings, I discuss them in relation to three current policy reports on disease prevention and prescribing. My study adds knowledge about a central part of modern primary care, based on suggestions of how the currently dominating approach in CVD prevention might shape people's perspective of medicines.

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## Abbreviations

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CVD	Cardiovascular disease
GP	General Practitioner
MOT	Mandatory test of motor vehicle safety, roadworthiness aspects and exhaust emissions required in Great Britain
NHS	National Health Service; the publicly funded health care system in the UK
NICE	National Institute for Health and Care Excellence; agency providing national guidance for health and social care in the UK
NNT	Number Needed to Treat; statistical term that describes the effectiveness of medicines
NYHA class I-IV	New York Heart Association classification of heart function, where I is heart disease without symptoms and IV is severe limitations and symptoms while at rest
OTC	Over The Counter; medicines that are available to buy without a prescription
QOF	Quality Outcomes Framework; incentive programme for general practice in the UK that awards points for prevention and management of disease and the quality of health care services
QRISK2, Q-risk test	CVD risk score that includes age, gender, ethnicity, smoking status, medical history, cholesterol, systolic blood pressure and body mass index

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And finally, thanks to Matt for being by my side – that is what makes it all worthwhile.

## A piece of wood

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I reach for a piece of wood. It turns into a lute.

I do some meanness. It turns out to be helpful.

I say one must not travel during the holy month.

Then I start out, and wonderful things happen.

*Rumi (1207-1273)*

*Translation by Coleman Barks (2004) Rumi; Selected poems. London: Penguin Classics*



# Chapter 1

## Introduction to the research problem and this study

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### **1.1 Chapter overview: Introducing my research**

In this thesis, I present my research into patients' understanding of the use of medicines in cardiovascular (CVD) risk management. It starts with an introduction of the research problem that I will address: polypharmacy as a result of increasing prescribing in primary care, which has the potential to cause both positive and negative effects.

The research presented here is informed by a critique against the expansion of biomedical interventions into more and more areas of human life. It also draws on research into patients' practical and emotional engagement with medicine-taking. Although exploring a research question that is formed in response to current medical practices and issues, it has its theoretical background in medical sociology. Therefore, this thesis contributes new knowledge that complements the biomedical model of CVD risk management, while also testing a recently suggested theoretical framework for describing the present driving forces behind increased prescribing of medicines.

In this first chapter, I explain the background reasoning for the research and how I decided on a setting to conduct my study. The chapter introduces the research question that is addressed in the thesis, and the aims and objectives which define how I set out to answer it. Finally, I give an overview of the remaining chapters, showing the structure of the thesis.

### **1.2 The research problem: Polypharmacy is a challenging part of today's health care**

Polypharmacy is the use of multiple medicines daily by a singular patient.[1] Derived from the Greek and meaning 'many medicines', there is no universally agreed number of *how* many medicines are required for the term to be used. Neither is it specified if the term applies only to items prescribed for long-term use, or also includes medicines that are used for shorter periods; either prescribed or available over the counter.[2,3] Around four or five daily medicines is commonly used as the cut-off in the recent literature.[1,4] As an introduction to

my research field, I will start by giving an overview over the complex phenomenon of polypharmacy.

### *1.2.1 Prevalence and effects of polypharmacy*

Although the number of concomitant medicines that is regarded as polypharmacy differs between countries and research teams,[5-7] the trend seems to be towards increased prevalence.[8,9] A Scottish study of prescriptions dispensed in the community between 1995 and 2010 showed that the proportion of adults using more than five medicines daily doubled, and the proportion using ten or more medicines tripled.[10] Similar development has been reported from Sweden.[11]

With increased prevalence there has been increased interest in the effects of polypharmacy. Its benefits are recognised in management of conditions where combinations of medicines help to achieve control over short- and long-term outcomes, for example in type 2 diabetes, HIV and coronary heart disease.[12-14] However, the number of medicines prescribed to an individual is associated with an increased risk for adverse drug reactions and drug interactions for patients,[8,10,15-19] leading to morbidity, hospitalisation and mortality.[9,17,20] Polypharmacy also creates a potential burden of treatment carried by patients, requiring efforts to manage complex treatments and infringing on daily life.[21,22] The challenge that polypharmacy presents to the delivery of health care [3] has led academic and professional organisations to call for improvement of the current situation.[1,23,24]

### *1.2.2 Efforts to improve the situation*

From a medical perspective, challenges related to polypharmacy include the definition of the problem and identification of factors that contribute to it. Moreover, there is a need to understand the nature of the difficulties that polypharmacy bring about – whether they are practical matters of managing increasingly complex regimes or if they also involve questioning the appropriateness of medicines in various situations.

Awareness of the problems related to polypharmacy has spurred efforts to improve the situation, especially for key patient groups such as the elderly and people with multimorbidity.[4,25] Medical and pharmaceutical research has investigated polypharmacy from the angle of it being a threat to adherence (due to complex regimens), and therefore focuses on devising systems and tools to help doctors and patients manage multiple medicines in a safe way. Examples of such efforts are different sets of criteria for evaluation of clinical

benefit,[26-28] technologies to aid prescribing, [29] medication reviews [2,3,30] and tools like reminder charts for patients.[31,32] Aspects of the context around prescribing have also been investigated: influence of the format of guidelines [33] and style of medical practice [34] have been targeted in efforts to ensure quality in prescribing within health care systems prone to increasing polypharmacy.

Quality in prescribing is a central concept in medical approaches to manage polypharmacy. One report – Polypharmacy and medicines optimisation; making it safe and sound [1] – which is directed to health care professionals, suggests the need to differentiate between *appropriate* and *problematic* cases. Appropriate polypharmacy is defined from a clinical perspective, where multiple medicines are prescribed in line with best evidence and the patient has support to ensure that they are taken correctly. Correspondingly, problematic polypharmacy is the prescribing of multiple medicines where the intended benefit is not realised.

### *1.2.3 Remaining gaps*

However, polypharmacy is an issue that involves many perspectives and actors, and therefore it is a complex issue to research. As discussed above, it has the potential to cause benefit as well as harm for patients.[1] There is a growing body of knowledge about specific aspects of polypharmacy, for example its prevalence, association with certain conditions and consequences in terms of adverse events. However, the research to date focuses on improving the medical management of medicines use and thus retains a professional and biomedical perspective. In addition to the biomedical aspects of polypharmacy, health care and medicines are also important institutions of today's society, which adds influences from the social world to the possible understandings of the phenomenon. A significant gap lies in understanding the use of multiple medicines from a patient perspective – including practical strategies applied by individuals in daily life and the influence from lay views of health, illness and medicines. With the research presented in this thesis, I seek to add to the knowledge about the complex issue of polypharmacy by exploring it from the perspective of patients.

## **1.3 Theoretical background**

Indications of iatrogenic problems caused by polypharmacy, in the form of harm from excess medicines and a growing burden of treatment [35] are signs that the efforts within medicine and pharmacy to improve the situation are not effective enough. From the inception of the

research project that is presented in this thesis, my approach was that it would critically examine polypharmacy from a different perspective than the biomedical, and thereby potentially suggest why prescribing continues to increase despite the awareness of a growing burden of treatment. For a theoretical background against which such a study could be planned, I turned to medical sociology. It has a long tradition of examining the social structures surrounding and interacting with concepts of health and illness, and the interaction between people and medicines.

### *1.3.1 Patients' reasoning and decisions about medicines*

Patients' usage of medicines can be seen as taking place at an intersection of medical science and daily lives. The biomedical evidence-base that underpins prescribing is introduced via health care professionals' choice of diagnosis and medication, and also in instructions about how to use the pharmaceuticals. Patients' following (or not) of such instructions has received much attention as an important factor for the outcome of treatment.[36,37] However, the notions of 'compliance' or 'adherence' (patients following prescribers' orders about how to take medicines) are also criticised for its inherent acceptance of the medical view as superior.[38] Sociological considerations of the phenomenon include such aspects as the meaning patients attach to medicines and how non-compliance can be seen as a result of a different process of reasoning, rather than failure to understand the medical rationale behind prescribing.[39,40]

This reasoning informs patients' decisions about whether or not to incorporate the medicine-taking into daily activities, where advice given by health care professionals may get combined with patients' personal understanding of practical, social and moral aspects of using medicines.[39,41,42] Issues like class, race, gender and age may also influence the role medicines play in health and illness.[43,44] Recent additions examine the impact of systems-factors such as health care organisation and governance, regulatory mechanisms and the influence from media and pharmaceutical industry, which are discussed below.[45-48] Important background for my study of polypharmacy from a perspective that also includes social influences (see section 1.2.3) also stems from Britten's work on the role and meaning of medicines in society.[41] For my examination of CVD risk management from a patient perspective, with the aim of finding explanations for how medicines are used, the starting point was the concept of medicalisation.

### *1.3.2 Medicalisation*

Medicalisation emerged as a term in the 1970's, drawing on examinations of the application of medical scientific practices to social life and experts' dominance over lay people as a form of social control.[46,49] It developed in response to an expansion of medical definitions of various aspects of life, most notably behaviours that were deemed deviant and thereby a threat to society.[50] Conrad [51] suggests the following definition: "defining a problem in medical terms, usually as an illness or disorder, or using a medical intervention to treat it". Medicalisation recognizes the power exercised by medical professionals by means of surveillance, diagnosis and prescribing. The expansion of that power into more and more areas of life while defining the experiences of health and illness and diminishing people's own abilities to handle such matters, following the contributions from Zola [52] and Illich [53] are central themes to the concept.

### *1.3.3 Pharmaceuticalisation*

Recent development of the understanding of medicalisation in today's society points to the altered driving forces behind expansion of medicine, the practice and consumption of health care and the role of medicines. Parallel to globalisation of markets and the introduction of market forces into the health care sector (among other areas), attention is given to the influence of the pharmaceutical industry over how medicines are developed and used.[49,54,55] This development of the concept, termed pharmaceuticalisation, [54,56] takes into account the changes in society towards more focus on the individual, with correspondingly less importance of the state or traditional social structures.[46] In doing so, pharmaceuticalisation includes other areas than medicine as influential, and explorations of the concept include both micro- and macro levels. Examples of the former is the permeation of medicines into areas of daily life and their role in the shaping of identities and consumption related to matters perceived as health-related.[57,58] On the larger scale examples include the role of legal systems for the distribution of medicines within society [45,59] and investigations of the 'pharmaceuticalisation of public health' discuss the role played by the pharmaceutical sector, governments, non-governmental organisations and local communities.[46]

Williams and colleagues [56] have suggested a framework of six dimensions for examining how pharmaceuticalisation takes place, showing possible links between the use of medicines and non-medical aspects of the world; things like expectations, identities, communication and legislation:

- *Selling sickness? The redefinition and reconstruction of health problems as having a pharmaceutical solution.* One reason for the increase in prescribing is that more conditions are defined as related to disease, and thus become indications for prescribing. This expansion of the market for medicines is driven by pharmaceutical companies that simultaneously promote conditions and the treatment for them. Efforts to increase sales of pharmaceuticals are directed towards individuals as well as health care professionals, and presented as education and research.[60]
- *Changing forms of governance: globalisation and the new role of regulatory agencies in promoting innovation.* It is recognised that political processes contribute to how pharmaceutical industry has gained influence over the way that medicines are developed and approved. One effect is that drug manufacturers dominate the large trials that influence clinical guidelines for diagnosis and prescribing.[45,61-63]
- *Mediation: the (re)framing of health problems in the media and popular culture as having a pharmaceutical solution.* Public understanding of the need for, and value of, medicines is shaped by how disease and treatment are presented in the media. Aspects such as self-diagnosis, celebrity endorsement and representation of personal accounts from both patients and professionals contribute to how diseases are perceived, and the media are powerful communication tools for the pharmaceutical industry and other organisations. In addition, social media offers platforms for individuals to share stories that include medicines, which might contribute to others' understanding of the products and their place in health and illness.[64]
- *Patients, consumers and the life world: the creation of new social identities and the mobilisation of patient or consumer groups around drugs.* Extensive marketing of medicines via popular media and patient advocacy groups has contributed to the role of the patient as knowledgeable and powerful actors in health care, but also places responsibility on individuals to manage their health with medicines. People are encouraged to take greater part in their treatments by becoming 'expert patients'.
- *From treatment to enhancement? The use of drugs for non-medical purposes and the creation of new consumer markets.* Medicines are being used to normalise, repair and augment [55] aspects of life, health and bodies in a process where the boundary between medical and social arguments for using pharmaceuticals is re-negotiated.
- *Pharmaceutical futures in the making: drug innovation and the colonisation of health futures.* This dimension deals with how the future is shaping the present; how

expectations of pharmaceutical products for intervention influence the actual flow of resources and thereby drive drug development and inform policy.

## **1.4 Choosing a setting for researching polypharmacy in UK primary care**

In my effort to research the complex phenomenon of polypharmacy in UK primary care, I have chosen to focus on one particular way of using medicines and set out to offer a thorough investigation of it, namely the use of medicines in cardiovascular risk management. Below, I give an overview of the epidemiology of CVD in the UK, and the strategies applied in prevention. This serves as a background for outlining the reasons for my choice of research ‘setting’; why CVD risk management is a useful topic to research in order to learn about a complex way of using medicines and therefore in understanding polypharmacy.

### *1.4.1 Epidemiology of CVD in the UK*

CVD is a leading cause of death in the UK among people both under and over 75 years [65-67], and mortality and morbidity rates resulting from CVD are higher in deprived areas.[65,66] Risk factors for CVD consists of fixed ones; age, gender and family history of CVD, and preventable ones that relate to an individual’s lifestyle; smoking, lack of physical exercise, harmful consumption of alcohol, low intake of fruit and vegetables and obesity. Physiological risk factors that contribute to a person’s CVD risk are high blood pressure, elevated blood cholesterol, diabetes and chronic kidney disease.[66] The association between lifestyle behaviours and CVD mortality and morbidity may explain the distribution of cases between social classes; those that are deprived have a higher risk of dying and experiencing illness from CVD.[66]

Management of CVD and CVD risk is also a major reason for prescribing medicines in the UK, with various types of anti-hypertensives (medications that control the blood pressure) and statins (which lower blood cholesterol) being among the most prescribed products in England, Scotland, Wales and Northern Ireland.[68-71]

### *1.4.2. Prevention strategies*

Since many deaths and cases of morbidity from CVD are preventable,[66,67] preventive efforts are prioritised in the NHS.[23] Historically, the implementation of evidence based risk management strategies has contributed to a significant decrease of CVD mortality.[67]

Cardiovascular prevention can be divided into two types; primary and secondary. Primary prevention of CVD aims to reduce risk factors in people without heart disease, with the goal to prevent events altogether,[72,73] whereas secondary prevention is interventions that reduce the risk of recurring events in people that have established CVD.[73,74]

The principles behind primary prevention of CVD were outlined by Rose in 1981.[75] He described how the rationale for preventive interventions depends on the prevalence and distribution of risk factors in a population,[76] and contrasted ‘high risk’ strategies directed towards individuals with ‘low risk’ strategies that encompass the population as a whole. The high risk strategy entails prescribing of medications and lifestyle changes to a relatively small group of people at considerable risk for CVD. These patients need to actively engage with the intervention (take medicines and change habits) for it to be effective. In return, they would be likely to benefit from the changes, since reduction of a high risk is strongly associated with fewer acute events. Low risk strategies instead aim to decrease the overall prevalence of risk factors in the population. They thereby achieve a smaller reduction of CVD risk in each individual but decrease the number of events in the population as a whole. Rose used reduction of salt in food as an example of a low risk strategy and pointed out the advantages of social pressure to decrease people’s use of tobacco. In terms of number of lives saved by CVD prevention, Rose concluded that the low risk strategies would produce a better outcome since the number of people at low risk is so much larger than the number of people at high risk. However, low risk strategies depend on people’s acceptance of broad-ranging interventions from which individual gain is difficult to demonstrate.

#### *1.4.3 The NHS Health Check*

A tangible example of preventive efforts in primary care is the NHS Health Check, which aims to reach all English citizens between 40 and 74 years of age.[77] This national programme for risk assessment and management entails measurement of blood pressure, cholesterol and body mass index and records age, ethnicity, smoking status, physical activity and medical family history. In addition to assessing the risk for CVD, it also screens for diabetes, kidney disease and dementia, and is described on the NHS public website as a ‘midlife MOT’.[78] The programme is presented as focus on promoting lifestyle changes and primary prevention, thereby reducing the need for medications in CVD risk management.[72]

Questions remain regarding the value of general screening programmes for common health conditions, like the NHS Health Checks.[79,80] A Cochrane review found no evidence that



such checks are effective in improving health in terms of for example mortality, hospitalisation, disability or absence from work. However, there was an indication of general health checks leading to more diagnosing and more prescribing.[80] In the case of CVD, the programme's predictions build on risk assessment and calculations,[81] and thus cannot predict individuals' risk for events which has raised questions about the sensitivity and specificity of the strategy.[79] Moreover, the limited coverage of the health checks particularly in some of the groups that might have an elevated risk (smokers, some ethnic minorities) jeopardises its value as a preventive strategy.[79,81] Critics of the NHS Health Checks have found it expensive with regard to its effects on mortality,[79] and ineffective in terms of its capacity for leading to sustained changes in behaviour among people at risk.[81] The policy has also been criticised for not evaluating the limitations or possible negative effects of the programme [82] and for medicalising CVD risk.[79]

#### *1.4.4 Changing approaches in primary care*

The broad introduction of NHS Health Check is representative of a changing approach to CVD risk management in UK primary care. Traditionally, the UK has used a high risk strategy for CVD prevention, and focused services on secondary prevention and specific target groups.[72,83] However, a shift towards more primary prevention has occurred in the last decade, with the Department of Health, the NHS and Public Health England stating that prevention of disease needs to be prioritised over treatment.[23,65] Individuals are encouraged to eat well, be physically active and avoid tobacco and alcohol.[72,84] Improved population health by means of prevention of disease is also put forward as a cost-effective way to use the resources within the NHS.[23,65]

Some aspects of the current strategy for CVD prevention are linked to the knowledge gaps regarding polypharmacy (see section 1.2.3) and also highlight issues associated with pharmaceuticalisation (see section 1.3.3). More specifically, these relate to the biomedical discourse of CVD as a driving force behind increased prescribing, and the challenge of balancing possible benefit and harm from medicines when considering not only populations but also a patient perspective on prescribing. These aspects set the scene for my research, and are described below.

#### *1.4.5 Increased prevention leading to increased prescribing*

Many CVD risk management regimens include multiple medicines,[1] and thus have the potential to introduce polypharmacy to a large number of people. While increased polypharmacy is often attributed to an aging population (which is presumed to have more diseases),[2,11,85] the pattern of how conditions are diagnosed has also changed.[35,80] In parallel to the emphasis from policy-makers on primary prevention, more data has been made available that supports the lowering of biomarkers with medicines also in people at low risk for CVD.[61,86] Widened diagnostic criteria have been criticised as a driver of prescribing, since they classify people that were previously considered healthy as needing medicines.[35] After the initial success of medicines against high blood pressure and cholesterol, lowered treatment targets and thresholds for intervention have been introduced as more data has been made available rather than in response to clinical demand.[61]

As mentioned above, current research about polypharmacy is largely focused on biomedical and professional aspects of the use of medicines. For example, the suggestion to define appropriate polypharmacy from problematic polypharmacy uses clinical benefit as the criterion for justifying the need for medicines.[1] However, what is considered appropriate can be subject to how the assessment of effect is done: pharmaceutical intervention may be deemed beneficial due to its net effects on the population level while the situation for individuals within the cohort can encompass both benefit and harm from medicines. In CVD risk management, the preventive effect will be tangible for some patients (who avoid a heart attack or stroke) whereas other patients experience no difference or suffer from side effects.

Regarding the balancing of benefit and harm, which is central to any pharmaceutical intervention, it has been suggested that the biomedical tradition for defining, producing and reviewing data about medicines promotes a dominance of positive effects discernible on the population level over individual perspectives on health and medicines.[87] An effect of this focus in drug development is that the priorities may differ from those of patients. Applied to CVD risk management, the dominance of a biomedical discourse will mean that the potential benefit from medicines is given close attention, whereas potential harm (such as side effects and treatment burden) is less carefully considered. This may influence the balancing of positive and negative outcomes in the decisions about prevention policies in a way that favours more pharmaceutical intervention. Fontana and colleagues, who addressed UK patients' acceptance of medicines for primary prevention of CVD, show the limitations of a biomedical model in explaining the actual use of medicines.[88] In contrast to the low level of harm from medicines that is assumed in clinical guidelines, they found patients to turn down a hypothetical risk

management treatment on the basis of not finding the potential for gained longevity making it worthwhile to take a medicine for the rest of their lives.

The changed diagnostic criteria in CVD expand pharmaceutical markets and introduce more medicines to more people [61] – many of which have not experienced any cardiovascular problems. Since one of the original aims in my research was to explore polypharmacy from the view of patients, the particular features of CVD prevention for individuals also guided the development of my research question. These are summarised below.

#### *1.4.6 Researching patients' perspectives on CVD risk management prescribing*

As mentioned above, the population approach to CVD risk management depends on individuals' acceptance of a preventive strategy. When prevention entails prescribing of medicines, it therefore requires the active participation – taking medicines daily – of people that become diagnosed as patients at risk for CVD. The extension of prescribing for the purpose of CVD risk management to include people without symptoms of illness introduces medicine-taking to an increasing number of people that are unlikely to benefit from them.[35,79,89] The low risk strategy (described in section 1.4.2) also means that benefit from treatment is realised on the population level, but not discernible for individual patients.

In CVD prevention, a lower level of initial risk makes it less likely for a person to benefit from risk reduction.[75] The absence of symptoms in people at low risk might also make medicine-taking seem questionable, as there is no illness to “try and get rid of”. On the other hand, the potential for side effects is the same regardless of CVD risk level.[75] The balance between potential future benefit and current harm from medicines therefore becomes contentious when people at lower risk are considered for pharmaceutical intervention.[35] Researching CVD risk management in primary care offers an opportunity to explore how patients perceive, value and balance possible beneficial and harmful effects from medicines in situations where symptoms of illness are not necessarily framing their experience.

### **1.5 Research approach**

In this project, I set out to expand the knowledge on polypharmacy and patients' views of medicines, while also contributing to the development of the concept of pharmaceuticalisation by critically reviewing it in a particular setting. Moreover, inspired by the concrete challenge

that CVD risk management prescribing and polypharmacy presents to both patients and health care professionals, I wanted to create new knowledge that had the potential to be useful in primary care practice. For this purpose, I used a combination of approaches which are discussed below.

The reasoning about what knowledge that needed to be created in order to suggest a more useful “patients’ perspective” of polypharmacy and CVD risk management, which guided my planning of the study, drew on Maxwell’s descriptions of critical realism.[90,91] Such a position combines a realist ontology with a constructionist epistemology. This means that it acknowledges the existence of a world that exists regardless of our knowledge about it, while also recognising that any type of understanding of the world depends on perspectives and viewpoints, and therefore is constructed in relation to things like experiences and interpretations. It challenges the notion that only observable, measurable phenomena and relations can be known and used in claims about reality.[92,93] In addition to a physical world that can be predicted and controlled, it acknowledges the influence of social structures in which individuals form their understanding and perform actions.[94] Here, my approach was also informed by elements of social constructionism – notably, the suggestions that the “idea” of CVD risk management takes shape in reciprocal interaction with the institutions, practices and individuals that engage with it in some way.[95] This perspective influenced my methodological position, insofar as pointing to the value of researching medicines use with a view that was open to such multi-directional relations.

In terms of examining the use of medicines in CVD risk management, the realist ontology accepts the presence of risk factors in people’s bodies and physiological effects of medicines – these phenomena have real qualities that exist independently of whether they are characterised; they are not merely social constructs that depend on particular situations. However, the constructionist epistemology adds that there is no independent knowledge about this real world. Therefore, the biomedical description of CVD risk and medicines is one, but not the only, possible and valid knowledge about it.

Drawing on the critical realist reasoning meant I set out to explore patients’ views on CVD risk management medicines with the understanding that also such things that emerges from people’s own accounts can add valuable knowledge about the researched phenomenon.[91] Since I aim to explore patients’ understanding of medicines while recognising that medicine-taking takes place in the context of people’s daily lives and under possible influences from

society, power relations and personal experiences of health and illness, I adopted an epistemology that recognizes that ‘truth’ about the world is related to the one that knows, and changeable due to shifting perspectives. In contrast, a study performed within the biomedical tradition, with a strictly empiricist view on knowledge about CVD risk management, would apply the condition that new knowledge about medicines use needs to be expressed in terms that derive from a biomedical description of the world. The biomedical definitions of medicines have their origin in a positivist paradigm where one ‘truth’ about the world is recognised and where new knowledge is sought in empirical experiments designed to confirm or reject hypotheses.[96] Examples of this approach to polypharmacy are seen in the efforts to define *appropriate* polypharmacy from *problematic* on the grounds of clinical definitions – descriptions of benefit stemming from medical science itself are used to assess its effects, while aspects that are not situated within medicine are not considered. As argued by Maxwell and Mittapalli,[90] such a view could be seen as restricting the type and scope of questions which can be asked, thereby restricting the ways of expanding knowledge.

Drawing together the background for my study – the questions prompted by increased prescribing alongside the awareness of effects from ‘too much medicines’,[97] the theoretical suggestions regarding pharmaceuticalisation [54,56] and the decision to examine polypharmacy from a perspective guided by critical realism [90,91] – the following considerations helped me formulate a research question:

- Prevention of CVD morbidity and mortality in the population requires large numbers of people to take medicines before any sign of ill health. With the apparent discrepancy between experienced and diagnosed health, I wanted to find out how patients respond to the ‘role’ assigned for them by a prescribing practice that is directed by population-level outcome targets.
- The beneficial effect from risk management medicines decreases at lower levels of risk, whereas the potential for side effects from medicines remains the same. As medicines are suggested to people at lower risk, I wanted to understand what patients expect the medicines to do for them.
- From an individual perspective, the use of medicines includes more aspects than the biomedical. By focusing the research on patients’ views and drawing on a combination of theoretical and methodological perspectives, I wanted to form conclusions and suggest explanations about the implications of

prescribing practice for individual patients that are useful and viable in clinical and other contexts.

Initially, this study was designed to compare GPs' and patients' perspectives on polypharmacy in CVD risk management. As the study developed, I instead chose to explore different aspects of patients' views. This was due to the realisation that an investigation that focused on patients would be enough to contribute new knowledge regarding the use of medicines. Since my early reading and ideas for research questions were all centred on patients' role in medicines use, I deepened this perspective throughout the project, rather than changing it to include practitioners. Four interviews with GPs that I held at the start of this project are not formally analysed and included as data in the study, but as they provided some suggestions about professional views on CVD risk management they were useful as background material. A summary of the interviews is available in appendix A1.

## **1.6 Aims and objectives**

The aim of this study is to understand the experience and role of patients in large-scale primary care prescribing for prevention of disease. My research question is "What are the influences on patients' understanding of the use of medicines in cardiovascular risk management?" The research question translates into the following objectives:

- To understand the existing known influences on patients' overall expectations of medicines, through a review of the scientific literature.
- To examine societal influence on peoples' concept of CVD risk management, through a critical review of a current case study (the debate about the extended prescribing of statins) as presented in newspaper articles.
- To understand individual experience and translations of expectations and knowledge regarding medicines for CVD risk management, through interviews with patients.
- To integrate the findings from the three studies mentioned above, and present an account of implications for prescribing for CVD risk management from an individual patient perspective.
- To suggest the implications of my findings for health care practitioners, policymakers and scholars working on pharmaceuticalisation.

## **1.7 Outline of the thesis**

In the present chapter, I have introduced the research topic of polypharmacy and the setting in which I intend to explore it, which is CVD risk management in UK primary care. Moreover, I have described the theoretical background for my study; the critique against increased prescribing formalised as pharmaceuticalisation, and how I will draw on a critical realist perspective in researching patients' understanding of medicines.

Chapters 2 and 3 consist of two literature reviews; one of scientific publications and one of newspaper articles. The first review explores patients' expectations of medicines. It concludes that they are influenced by more aspects than those that are represented in a biomedical model of medicines use, and that individual experience plays a major part in patients' understanding of medicines. It also identifies a lack of knowledge regarding patients' concepts of CVD risk management, and concludes that this will be addressed in the empirical part of this thesis. The second review considers one of many non-medical sources that inform lay understanding of health and medicines. Here, I use the timely revision of the NICE clinical guidelines for cardiovascular risk assessment and lipid modification to explore how policy-makers' and medical professionals' statements are transferred into a lay context. It explores the tension between individual and population aspects of risk management medicines, and looks at how CVD risk and its containment are described in a popular context.

Chapter 4 describes the methods in my empirical study. After outlining the methodological approach for creating new knowledge about my research topic, I describe the process of recruitment and sampling of participants and how data were collected in interviews. The chapter also contains a detailed account of how I organised and analysed data in order to present my account of patients' understanding of medicines in CVD risk management. Finally, I show how I will assess the validity of my findings by discussing their applicability to this particular field and their transferability to other areas of medicine.

Chapters 5 and 6 present the findings in the empirical study, with one major theme in each chapter. The themes, sub-themes and categories are displayed alongside quotes showing how participants shared experiences and stories about medicines during the research interviews. Personalised representation of causes and consequences, individual responsibility following diagnosis, the necessity of taking action, experience-based reasoning and stability as confirmation of benefit are the major points that form patients' understanding of CVD risk management medicines.

In chapter 7, I combine the findings from the two literature studies and the empirical research to consider how they contribute towards a new account of patients' views of CVD risk management medicines which is based on individuals' experiences and understanding. The main themes throughout the study are presented, and I discuss what the new knowledge adds in terms of how to approach CVD risk management prescribing and polypharmacy in primary care.

Finally, in chapter 8 I critically review the trustworthiness of my findings in relation to the research problem, strengths and weaknesses of the methods I used and my positionality as a researcher. Some interesting aspects of risk management and prescribing that have been present in this study without becoming part of the main research process are pointed out as suggestions for further research. To conclude, I revisit the starting point for this thesis – how knowledge about patients' views of medicines might contribute to better understanding of the complex phenomenon of polypharmacy.



## Chapter 2

### Patients' expectations of medicines – a review and qualitative synthesis

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#### **2.1 Chapter overview: turning to the literature**

One thought that informed the direction of the research underpinning this thesis was “what makes people accept risk management medicines, despite the small individual risk reduction and the lack of tangible benefit?” To start investigating what might be taken into account in patients' balancing of risks and benefits in decisions about whether to use medicines, I undertook a review of the literature on factors that influence patients' expectations. It draws on two comprehensive descriptions of the formation of expectations on health care matters and includes primary research into the use of prescribed medicines for a number of symptomatic conditions. The review is presented and discussed in this chapter. A version of this text was published as a review article in *Health Expectations* in January 2015, see appendix A2.

This review and synthesis of the literature informed my further work by outlining the mechanisms at play in patients' understanding of effects from medicines. The findings also gave rise to questions about how future benefits from medicines prescribed to manage risk conditions are conceptualised, which informed my empirical study.

#### **2.2 Patients' expectations**

Treatment for the purpose of management of risk for future disease often targets asymptomatic conditions. Benefit from this type of prescribing is established on the population level, but not necessarily demonstrable for individuals. In addition, beneficial effects require long-term commitment to therapy by large numbers of people. Considering the absence of illness symptoms and subsequent remedy from this type of prescribing, I wondered what may make patients accept medicines for the purpose of risk management. As shown by the medical sociology literature, a health care professional's instruction based on a biomedical model of risk and benefit might not be enough of a rationale for patients to engage with treatment.[41]

The concept of pharmaceuticalisation suggests that expectations of effect and benefit from pharmaceuticals are an important driving force for increased use of medicines.[56] As risk

management prescribing considers actions related to future events, I therefore decided to use patients' expectations as a central point in the examination of their understanding of this phenomenon. Given my critical realist perspective, my review of patients' expectations focused on what might influence such expectations, acknowledging that personal and social circumstances might be part of how people understand, and engage with, medicines.

In a meta-ethnography of lay experiences of medicine-taking for a number of symptomatic conditions, Pound and colleagues present the expectations patients have in relation to treatment of a number of long-term conditions.[98] Hopes and expectations of benefit are named as an important factor in the evaluation of medicines: they relieve or control symptoms, avoid relapse or hospitalisation, slow or halt disease progression, prevent future illness or bring normality.

In a theoretical description of the influences on patients' expectations on medicines, Thompson and Suñol emphasise the combination of cognitive and affective components and outline a range of personal and social factors that interplay with the information provided in a health care context.[99] These include needs, values, experiences and emotions, as well as social norms, conditions and restrictions. Four types of expectations are identified: Ideal, predicted, normative and unformed (see figure 2.a).

Type of expectations	Characteristics
Ideal expectations	Desired or preferred outcome based on idealistic beliefs regarding what a medicine can provide
Predicted expectations	Anticipated, realistic outcome based on personal or vicarious experience and other sources of knowledge
Normative expectations	What the patient thinks should or ought to happen, based on evaluation of what is deserved or socially endorsed
Unformed expectations	Inability or unwillingness to formulate what is expected due to fear, social norms or lack of knowledge
<b>Health care context-specific features that influence expectations</b>	
Long-term relation between patient and doctor Patient's emotional state may be shaped by illness experience and coping strategies Patient's knowledge about the condition and the effects of medicines may be very limited at the outset of a treatment, but increases over time Patients tend to use a subjective rather than objective set of notions when evaluating effects and services	

Figure 2.a Classification of patients' expectations suggested by Thompson and Suñol [99]

Using these two models as a theoretical framework for how expectations are formed, formulated and related to experiences, I set out to review the literature on patients' expectations with the aim to produce an account of mechanisms and influences. The two research questions in this particular part of the study were "What are the influences on patients' expectations regarding prescribed medicines?" and "What benefits do patients expect from medicines prescribed for long-term prevention of disease?"

## 2.3 Methods

### 2.3.1 Search strategy

The database searches were set up to explore possible influences on patients' expectations of medicines. By using broad search terms I aimed to capture multiple aspects on the research questions so that a comprehensive account could be formed.

Searches were done in two stages. In the first step, I explored influences on patients' general expectations related to prescribed medicines. To find out specifically about treatments for the management of risk for future disease, the second step focused on patients' ideas about benefits with medicines prescribed for preventive purposes. Search terms are outlined in table 2.1. Searches were performed in Medline and Scopus during August and September 2013 for publications from all available years.

Table 2.1 Search terms

Research question	Search terms	Hits
What are the influences on patients' expectations regarding prescribed medicines?	expect*AND influence* AND patient* AND prescribing OR prescription	614
	expect*AND patient* AND primary care AND prescribing OR prescription	135
	influence* AND qualitative research AND prescribing OR prescription	427
What benefits do patients expect from medicines prescribed for long-term prevention of disease?	benefit* AND expect*AND qualitative research AND prescribing OR prescription	225
	benefit*AND expect* AND medicine* AND patient* AND prevent*	122

### *2.3.2 Selection of publications*

The first step in the selection was scanning of article titles. Abstracts and full-text articles were then checked for descriptions of patients' accounts of using medicines and descriptions of influences on expectations. Due to the exploratory nature of this review, quality of the reported study was not used as a criterion for inclusion or exclusion. Instead, a careful examination of the applicability of the reported findings to the area of long-term prescribing was undertaken at the selection and synthesis stages.

Articles were included in the review if they explicitly addressed qualitative aspects of patients' expectations, beliefs, views or thoughts about medicines prescribed for treatment or prevention of long-term conditions and were written in English. Publications retrieved in the searches but excluded during the review process described practices or behaviours rather than views, professionals' expectations rather than patients', evaluations of specific interventions or solely quantitative aspects of patients' expectations. Articles about end-of-life care or medicines used for lifestyle or aesthetic purposes (obesity, facial acne, hair loss) were also excluded, on the basis that expectations related to these types of treatments are likely to be influenced by emotional factors that lie outside the scope of this research.

### *2.3.3 Extraction and synthesis of data*

Data extraction and synthesis of findings was done by open coding of reported influences on patients' expectations in the selected literature followed by a constant comparative thematic analysis [100] and synthesis.[101] The open coding was informed by, but not limited to, the aspects of patients' expectations on medicines discussed by Thompson and Suñol and Pound and colleagues.[98,99]

As recommended by Thomas and Harden for the rigour of a thematic synthesis,[101] context-specific information was recorded alongside the extracts in the first round of descriptive coding. Preserving links to the context in which data originate makes the aligning and synthesis of findings from various types of studies describing different illnesses more robust.

While examining each included article line-by-line for reports of any influence on expectations, I listed all such extracts in a spreadsheet together with study characteristics. The full list was then reviewed and extracts were assigned descriptive labels such as 'own immediate/practical need', 'testing', 'other people's views', 'belief' and 'medical information'. Extracts with similar descriptive labels could then be combined across studies and categorised thematically.

Here, the contextual information helped clarify how data extracts might describe aspects of the same phenomenon (and so be appropriate to combine) or only seemingly similar things (and so needing another look at where to put them). As an example, the list of descriptive labels contained many examples of specified outcomes that patients expected from medicines, but some of these originated from accounts of experiences and others were given as replies to hypothetical questions. Once the coded extracts had been collected under descriptive themes, they were compared on the basis of features that were less context-specific and more generic so that analytical categories reflecting features shared between separate studies could be assigned.

Data within the emerging analytical categories were compared for similarities, differences and contradictions so that as many aspects as possible of each type of influence was captured. Content was moved around to produce distinct and internally coherent characterisations of each type of influence on expectations. Finally, the categories were aggregated into themes that reflected their whole content. Thematic synthesis allows for themes to be formulated at a level 'beyond' description of the different types of data in separate studies so that new interpretations and explanations can be suggested.

Throughout the process of selection of publications, data extraction and synthesis I discussed the work and the emerging findings with Prof Walley and Dr Reeve. This served as guidance as it was my first attempt at qualitative analysis and synthesis of data, and also strengthened the interpretive validity of the findings. At the point of starting to formulate comprehensive themes, I began to write a descriptive account of the findings that was also shared with Prof Walley and Dr Reeve. This helped test the emerging story and identify dissonance and uncertainty that needed further exploration. In addition, the criteria for trustworthiness proposed by Lincoln and Guba were used as a framework for the critical assessment of the emerging analysis.[96]

## 2.4 Findings

Combinations of the search terms in titles or abstracts yielded 1428 unique records. After scanning article titles, 92 abstracts were reviewed which led to 27 full-text articles being assessed for inclusion. Reference lists in the reviewed papers were scanned for useful sources, which returned 23 more publications. The final synthesis included 20 publications, 12 of which were identified via databases and eight from the scanning of references. The selection process is shown in figure 2.b and data and contextual characteristics from the included articles are summarised in table 2.3 (see the end of this chapter).

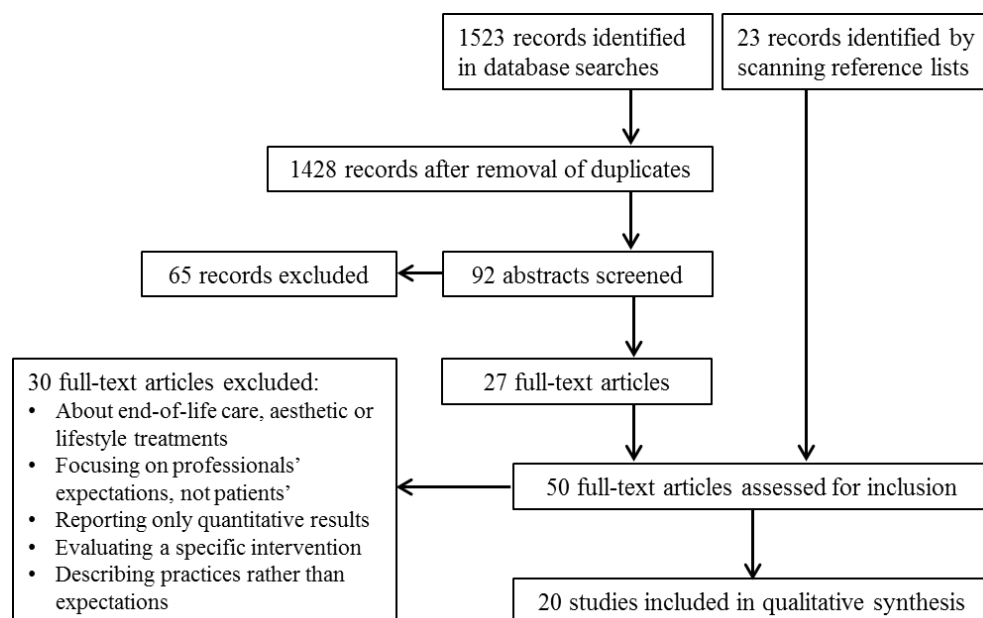


Figure 2.b Search results and selection process for articles.

Four themes were identified from my synthesis of the literature (see table 2.2). Influences on patients' expectations of medicines range from being highly specific and related to short-term targets that medicines are hoped to help achieve to general views on whether medicines are useful at all. Practical experiences, personal beliefs and other people's opinions are influential as expectations are formed and develop over time.

Table 2.2 Codes and themes

Theme	Examples of codes
A need to achieve a specific outcome	<p>Medicines relieve symptoms, help avoid hospitalisation, control disease or improve the conditions of daily life [39,102-104]</p> <p>Confirmation of effects is sought, and lack of identifiable effects can lead to the medicine being seen as not useful [39,103,105,106]</p> <p>Medicines offer something beyond what is achieved by diet and exercise [104,107]</p> <p>A medicine prescribed for prevention “stops a heart attack”, “cures the bones” or “does the job the doctor says need to be done” [103,108]</p> <p>Benefits with preventive treatments are overestimated [109,110]</p> <p>Patients wish for guarantees of survival [109-112]</p>
Experiences and evaluation developing over time	<p>Duration of illness influences understanding of disease and treatment effects [105,113]</p> <p>Past bad experiences of side effects triggers a conscious evaluation of risks and benefits when new treatments are suggested [105]</p> <p>Patients are seeking to confirm and adjust expectations [105,107]</p> <p>One’s own experiences and those of other people are used in decisions about medicines [103,104,107,108,113-115]</p> <p>Risks and benefits are balanced by patients in a different way than by doctors [105,108-111]</p>
Negative values – dependency, criticism and social stigma	<p>Fear of getting addicted, associations with illicit substance use [102,116]</p> <p>Hesitancy to be dependent on medicines for a normal life [39,116]</p> <p>The number of medicines used by one person can be seen as too high [105,106]</p>
A personalised meaning of medicines; their necessity and usefulness	<p>Medicines for different conditions are seen as being of different value [117]</p> <p>Patients with the same condition express diametrically different views about the treatment: necessary or of very limited value; as something that helps them to live normally or the only way to avoid death; as a choice based on experience or a resignation in lack of other options [102,104,116]</p> <p>Core health beliefs and notions of responsibility and morality influence decisions [103-105,118]</p>

#### *2.4.1 A need to achieve a specific outcome*

The first theme shows how patients' expectations are influenced by a perceived need to bring about change. Medicines are described as an instrumental way to relieve both specific and wide-ranging aspects of symptomatic illness by patients with depression needing to get better quickly after "hitting rock bottom", [102] and epilepsy, where the medicines control seizures as well as reduce worry. [39] Preventive medications are also seen as providing very specific benefits such as "stopping a heart attack" or "curing the bones". [103,108] Here, the change is not in the form of alleviation of experienced illness symptoms. Instead, medicines are expected to produce general benefits related to a condition that is defined by a medical professional. Even more general descriptions of medicines as effective tools to care for oneself beyond that which can be achieved with diet and exercise are shared in interviews with patients suffering from heart failure and osteoporosis. [104,106] These anticipations resemble a combination of the ideal and predicted expectations described by Thompson and Suñol. [99] In terms of expressing expectations, it has been suggested that this is predominantly done by patients looking for specific outcomes, especially in relation to a condition that greatly impacts on their daily lives. [103]

Another indication that specific changes are important influences is the need for confirmation of a medicine's effect by symptom relief or some other immediately observable benefit. Correspondingly, a lack of salient effect from the medicines may lead to loss of perceived meaning with the therapy in patients' views. This phenomenon points to the link between medicine-taking and relief of symptoms as an important motivator for patients. [39,98,105,106]

Patients' expectation that medicines will obtain certain effects also seem to apply to outcomes defined by someone other than the patient; both as a general 'they should do what the doctor says need to be done' [103] and more specifically mentioned by people with schizophrenia saying that medicines are used by doctors to control patients' behaviour and make it acceptable to society. [114]

An element of specificity also applies to the anticipated amount of effect. In relation to expectations on medicines for risk reduction several studies report that patients overestimate the possible benefits with preventive treatments: the anticipated reduction of risk for cardiovascular events and stroke in return for the effort of taking medicines every day is much higher than clinically possible and when provided with information about the likely level of benefit patients tend to decline treatment referring to potential side effects. [109,110]



In interviews with elderly patients about their willingness to use anticoagulants to prevent stroke, patients discussed the decision in terms of gambling and trade-offs and expressed wishes for a guaranteed number of disease-free survival years.[111] The format of risk and benefit information when suggesting treatment for the management of risk seems influential on patients' decisions about treatment: relative risk reduction yields much higher acceptance than number needed to treat (NNT) and disease-free survival stratified between groups of patients gave more positive responses than when presented in a summarised way.[112] The representation of benefits by absolute or relative risk reduction might be interpreted by patients as giving everyone a reduced risk, whereas with NNT one single person gets the whole benefit of survival, making it less appealing. An expressed desire for a guaranteed number of years and the gambling and trade-off language used by patients in discussions of the decision to accept or decline treatment also suggest that benefit is being conceptualised as a specific effect or event that is delivered by medicines.

#### *2.4.2 Experiences and evaluation develop over time*

The expectations placed on medicines seem to be influenced by previous experiences of illness and medicine usage.[39,105] Predicted expectations [99] dominate. These are weighted together in a continuous evaluation of whether and how to use the prescribed medicines and longer duration of illness seems to open up for a more nuanced description of expectations. A cyclical trial and evaluation, where patients balance their view on long-term medicine-taking with important experiences of improvement and worsening of their condition, make patients experts on their own treatment.[102] This evaluation includes factors from the medical realm such as information about the condition, possible consequences and prescribed medicines as well as factors from other parts of life. In comparison to medical professionals' evaluation of medicines' appropriateness, patients use a shorter time-scale when determining if a medicine has beneficial effects. Their acceptance of risks or symptoms in relation to possible side effects, and the number of aspects weighted into such decisions, also make patients' decision-making different from that stipulated by a biomedical model of health and illness.[108,113]

Aside from patients' own experiences, information from surrounding people is reported by several authors as influential on expectations. Doctors' advice [109,114] is balanced with personal and vicarious experiences, [104] whereas academics and pharmaceutical industry are seen as less reliable sources.[115] Development of trust in a prescriber seems to influence patients' decision to accept treatment, suggesting that it leads to expectations of beneficial

effects,[107,115] while patients that retain a more critical stance compare prescribing to experimentation and question the doctor's knowledge about how a specific patient's body works.[108] Consulting peers seems to be associated with patients being reluctant to accept treatment.[107,108]

Patients' balancing of perceived beneficial and harmful effects changes over time.[105,107] Even patients that want their doctors to make decisions about treatments state a desire to be informed about the anticipated effects in order to participate actively in evaluation of the effects. Information for this purpose is also sought from public sources and the health care system to confirm and adapt expectations.[103]

#### *2.4.3 Negative values – dependency, criticism and social stigma*

The third theme encompasses negative aspects of medicines that are not derived from personal experience but instead related to general, societal views. It contains aspects of normative and unformed expectations.[99] Certain types of medicines are described by patients as associated with addiction, dependency and illicit substance usage. Asthma patients describe negative associations evoked by illegitimate use of steroids by bodybuilders and depressed patients hold initial reservations about treatment due to fear of addiction and social stigma. Patients describe both their own views, those of family members and reports available in the public realm as negatively influencing the usage of medicines.[102,116]

The number of medicines used by one person is also reported as something that may be valued negatively and evoke criticism from others. Patients question the helpfulness of taking a large number of medicines every day [106] and may decline new suggested therapies on the basis that they are already using too many medicines.[105]

#### *2.4.4 A personalised meaning of medicines; views on their necessity and usefulness*

The fourth theme is built up by codes related to the perceived utility of medicines in patients' lives, beyond that of providing immediate effects. This encompasses longer periods of time and wider aspects of living with illness. A recurring feature in the dataset was the widely contrasting views patients share in relation to medicines' usefulness and necessity. This theme displays a combination of the four types of expectations described in figure 2.a.

When diagnosed with a chronic condition such as asthma or epilepsy, medicines can play the role of either aids to obtain normality, by giving the patient control over symptoms, or obstacles

cutting one off from normality by their association with social stigma and having an illness. However, such negative notions can be overcome by acquiring knowledge about a condition: steroids form an essential part of the management of asthma, and medication against depression or epilepsy becomes accepted as a way to get on with life.[39,102,116]

A number of authors address the question about whether medicines are seen as necessary for life, health etc. or if usage is optional, subject to personal inclination and should be balanced with lifestyle changes to help manage the condition. Patients with multiple conditions may regard some medications more necessary than others, or some as being essential and other optional.[117] In interviews with elderly women about osteoporosis medication some participants stated that the medication was an inevitable, normative way to treat a condition associated with old age and therefore it would be effective, whereas others claimed that the natural ageing of the bones would limit the effectiveness of medication. In more general terms, prescription medication was described both as a way to obtain something beyond what diet and exercise could bring and as a “last resort” that would only be used if those failed.[104]

In several studies medicines are described as a commitment and ‘part of life’ by patients with chronic conditions. However, this can have both positive and negative connotations. Heart failure patients interviewed about their associations with medicines report taking them without knowing what benefits they will bring but “because I don’t ever get better” or “otherwise I will die”. On the other hand, the medicines also allow patients to “complete things during the day” and “enjoy doing more things”. [106] Similarly, depressed patients described the decision to use medicines in the long term as a conclusion based on experience, or as resigning to them being the only way to get by.[102]

One way to reconcile the opposing views expressed by patients living with the same chronic condition is the conclusion that expectations on medicines are influenced by deeply held personal views. This is described in terms of core beliefs about health and illness and feelings of responsibility or obligation to use medicines when diagnosed with a condition.[105,107,118] Links between acceptance of treatment and demographic characteristics such as level of education or social class have been addressed and discussed by a few authors, but with inconclusive results.[110,118]

## 2.5 Discussion

This analysis identified four themes regarding influences on patients' expectations of medicines: a need to achieve a specific outcome; the development of experiences and evaluation over time; fear of dependency and social stigma; and personalised meaning of the usefulness and necessity of medicines.

### *2.5.1 Influences on patients' expectations*

The desire for observable short-term effects, usage of experiences and knowledge in a process of evaluation and notions of meaning linked to personal and societal values show that expectations on medicines are multi-dimensional and dynamic. A low acceptance for side effects, fear of dependency on medicines that do not have addictive properties and criticism against using a high number of medicines every day are influential factors that fall outside the biomedical model of health and illness.

In the specific case of expectations of benefit from medicines that are prescribed to manage asymptomatic risk conditions, my findings highlight a number of issues for consideration. Patients' desire for tangible benefits and specific outcomes in the first theme and the role of experiencing ill health and medication effects in the second theme highlight a potential lack of meaningful ways to relate to and engage with medicine-taking when the reason for treatment is a risk identified by one's doctor. An implication of this may be that patients interpret a decision about using such medicines as a dichotomous choice rather than as a way to influence the likelihood of outcomes. Another aspect is the perceived need for and acceptance of treatments for a growing number of conditions related to risk for future disease. The third and fourth themes point to possible issues regarding patients' acceptance of the concept of risk reduction by means of treating cohorts in order to decrease the number of acute events in a population. Prescribing of several medications, for example in order to get a patients' blood pressure within a target range, may be considered medically appropriate if there is evidence for possible benefit from all of them. However, patients' views that it renders a number of daily tablets that is "too high" or that higher blood pressure is part of aging challenges the notion of benefit. In a wider sense, the increased availability and prescribing of medicines that target risk for future disease might influence personal and societal values held about using medicines for preventive purposes.

Influences identified in my analysis mirror the ideal, predicted, normative and unformed expectations described by Thompson and Suñol [99] (see figure 2.a) and show how patients engage in practical evaluation of medicines as described by Pound and colleagues.[98] The synthesised data comes from one literature review and 17 primary data collections, representing several clinical fields and a range of qualitative aspects of medicine-taking. My synthesis therefore broadens the description of influences on patients' expectations on medicines. It helps progress the understanding of patients' expectations by highlighting the importance of evaluation of medicines from an individual perspective. This finding is important for the further development of a theoretical description of medicines used for the purpose of risk management.

### *2.5.2 Critical review*

Codes and themes also resonate with an investigation of the impact of long-term medicine-taking on quality of life published by Krska and colleagues just after the searches for this analysis were undertaken.[22] There, the authors identify wishes for tangible effects, usage of different sources of information to confirm expectations, trusting or challenging recommendations from one's doctor, fear of dependency and complex decision-making regarding the usage of a necessary but disliked medicine. As my review identified these themes across a range of publications describing different types of data, it adds weight to the research by Krska and colleagues. The identification of similar themes between the two studies also provides an indication of the transferability of the findings.

A methodological limitation of the presented synthesis is that although I had support from my supervisors in the decisions about searches and extraction as well as the coding and formulation of themes, the practical work was done by only myself. During the database searches it became clear that "expectations" is used liberally in the literature and it was difficult to specify narrow search terms that captured exactly what I was looking for. For this reason, searching reference lists of the included articles became an important way to identify publications. Another limitation, which is related to the difficulty of defining a comprehensive search strategy, is that only two databases were searched. Repeating the searches in PsycINFO and CINAHL, and using the same search terms and criteria for inclusion and exclusion, returned some of the already included articles but did not identify any more publications to include.

Other limitations are due to the diverse nature of the primary data in the included publications, which is derived from narratives, interview material and data collected via questionnaires and describe both personal experiences and statements about hypothetical scenarios. Although the

connection between using medicines and living with a long-term medical condition has been highlighted,[39,116] only a few of the included publications discuss this issue in relation to their findings. This makes it difficult to determine whether the data represent specific expectations of medicines or thoughts about health, illness and care in general. An example of this is the discussion of a relation between readiness to make a decision about starting treatment and acceptance of it in a couple of the included publications, where the decision-making process may be hampered by a patient's ambivalence *vis-à-vis* the diagnosis or the prescriber in clinical cases, and by difficulty to relate to the task in a hypothetical situation.

Assessment of truth value, applicability, consistency and neutrality helps determine the validity of findings in qualitative research.[96] The recursion of codes and themes between this synthesis and other investigations of qualitative aspects of patients' views on medicines is an indication of truth value and consistency of the results. However, the neutrality may be compromised by the fact that most of the included publications, although researching qualitative aspects of expectations, adopt a medical model where the aim to increase adherence to treatment becomes evident in the conclusions. Applicability of findings may differ between clinical fields. With regards to long-term management of risk, the reviewed literature contains descriptions of some elements that relate to patients' decisions to accept or decline medicines. However, gaps remain in the theoretical understanding of how benefits with such medications are conceptualised, and how this may interrelate to prescribing for such purposes. This gap will be addressed in the empirical part of my research.

## **2.6 Conclusions**

Unwanted effects of the increasing prescribing of medicines in the UK are the growing burdens of medication-related problems, waste and costs for patients and the NHS. In addition to interventions framed as medicines management, addressing the social aspects of health, illness and medicines could offer a way to understand and address more aspects of the increasing levels of prescribing in primary care in the UK.

The stochastic nature of usage of medicines for the purpose of risk management, where time to beneficial outcome and distribution of benefit in a group of treated individuals are impossible to predict, makes patients' conceptualisation of benefits an interesting and important but also under-researched element of prescribing. Whereas medical and economic arguments for risk

management medications can be gathered on a population level, findings in this qualitative synthesis suggest that individual patients are influenced by many more types of knowledge and values in a continuous, personal evaluation of whether to start and continue using medicines.

A deeper exploration of how patients conceptualise benefits with medicines prescribed to manage risk is the objective of the empirical part of my research, involving interviews with patients at different levels of risk for cardiovascular disease. Building on this review, the aim will then be to develop a fuller theoretical understanding of how this topic can contribute to improved usage of medicines.

Table 2.3 The dataset

Authors, year	Content
Schofield <i>et al</i> (2011)	<p>Context Semi-structured interviews with 61 patients recruited from GP practices in three areas in the UK. Eligible patients invited via a letter from their GP. All participants had been prescribed antidepressants against depression and/or anxiety for at least a year. Purposive sampling is used to reflect the population of users of antidepressants in terms of age, sex, ethnicity and socioeconomic background. Most participants had experienced several episodes of depression at the time of the interview.</p> <p>Findings</p> <ul style="list-style-type: none"> <li>- At the time of initiation of treatment, medicines were seen as a short-term measure to get better at a time when they really needed it.</li> <li>- Many participants had reservations against antidepressants when first consulting their GP, due to concerns about using medicines in the long term, fear of addiction and negative views held by themselves or others.</li> <li>- Using and experimenting with medicines over time makes patients experts on their own conditions and treatments. This expertise gives the patient more control over decisions regarding management of their illness.</li> </ul> <p style="text-align: right;"><i>(table continues overleaf)</i></p>

Conrad (1985)	Context	In-depth interviews with 80 people with epilepsy about the meanings of medications in everyday life and why medicines are taken or not, carried out as a part of a larger project about living with epilepsy. All participants were or had been using medications against the condition. Recruitment was done via community channels. Participants are described as between 14 and 54 years old, mostly lower middle class and coming from urban areas in the US. Interviews were held independent of medical and institutional settings.
	Findings	<ul style="list-style-type: none"> <li>- Peoples' practices regarding medicines are related to aspects of control in two directions: taking control over symptoms or worries about the disease, or being controlled by a disease that forces usage of medicines.</li> <li>- A continuous evaluation of the medicines is undertaken, and patients may stop taking them if no specific effect is perceived.</li> <li>- The author refers to a general view in society that it is better to try to achieve health goals without medicines, and reports reflections of this view in the participants' accounts.</li> </ul>
Dolovich <i>et al</i> (2008)	Context	The study aims to investigate expectations and influences thereon to find out if expectations have an impact on how medicines are used. Purposive sampling and recruitment through community and health care channels in Canada was used. The 18 participants represent different ages, living conditions and types of medicines used. Semi-structured interviews were conducted around the medicines the participant considered most important, and analysed using grounded theory.
	Findings	<ul style="list-style-type: none"> <li>- Expectations are most clearly expressed by patients who want a clearly defined outcome in a condition that affects their daily life</li> <li>- Participants are realistic in what they want medicines to achieve and use different sources of information to adapt and confirm their expectations.</li> <li>- The number of medications used every day was described as an issue; either as burdensome for an individual or in general terms.</li> </ul>
Unson <i>et al</i> (2003)	Context	With a stated aim to increase adherence, patients' beliefs about osteoporosis (OP) medication and medicines in general are assessed. Focus groups based on ethnicity was recruited via senior centres and housing estates in deprived areas in the US. A convenience sample of 55 women aged 60 years or older participated. Most participants were on prescribed medication, but not for OP. Authors suggest that what is handled as a dichotomous question (treatment or not) in medicine is a more complex decision for patients, where heuristics, moral aspects and power relations are at play.
	Findings	<ul style="list-style-type: none"> <li>- Side effects are considered serious and on a short term basis; "they can be worse than the disease itself" and "25% protection without side effects is better than 50% with".</li> <li>- Participants use both their own experiences and those shared by others in decisions about medication.</li> <li>- Scepticism about prescribers' knowledge about how medicines affect specific patients; prescribing partly seen as doctors' experimentation.</li> </ul>

*(table continues overleaf)*



Granger <i>et al</i> (2012)	Context	Mixed methods study aiming at exploring theoretical linkages between symptom experience over time and the meaning of medication adherence. Ten patients with chronic heart failure completed questionnaires measuring beliefs, behaviours, symptoms and satisfaction and were interviewed about the meaning associated with medicines. Patients were recruited by research nurses during an admission to a US university hospital with exacerbation of their condition.
	Findings	<ul style="list-style-type: none"> <li>- Experience of symptoms influences the meaning attributed to medicines.</li> <li>- Medicines are described in positive ways as tools to care for oneself, but also with negative notions of being inevitable if wanting to avoid death.</li> <li>- Patients questioning how a large number of medicines everyday can be helpful.</li> </ul>
Mazor <i>et al</i> (2010)	Context	Telephone interviews with women $\geq 65$ years that fulfilled WHO criteria for osteoporosis, recruited from a multispecialty practice in Massachusetts, US. History of dispensed prescriptions was used to classify participants into three groups of equal sizes: not using medication, started but discontinued medication and currently on medication. The study links core beliefs about medicines to patients' views on perceived need, safety and efficacy of a medication.
	Findings	<ul style="list-style-type: none"> <li>- The need and usefulness of medication is described as related to age, but with different conclusions: old age and brittle bones make medicines necessary, or offset the efficacy of medicines.</li> <li>- Patients that make use of peers' knowledge or experience of the medication are sceptical to treatment.</li> <li>- Connects participants' views on medicines with their core beliefs about health and illness.</li> </ul>
Nair <i>et al</i> (2007)	Context	Semi-structured interviews seeking to investigate patients' experiences with risk-benefit assessment when making decisions about treatment for type II diabetes. The 18 Canadian patients used different types of treatment and were recruited through community and health care channels. Both purposeful and theoretical sampling was used to ensure inclusion of patients that found treatment easy as well as difficult. The interpretation of the interviews was validated in a focus group session towards the end of the analysis process.
	Findings	<ul style="list-style-type: none"> <li>- Avoidance of medication may be based on the impression that one is already taking too many medicines.</li> <li>- Duration of illness and experimentation with medicines influences the understanding of the effects of disease and the treatment.</li> <li>- Patients develop a personalised understanding of the value of a treatment, and this forms a basis for the decision whether to use a medicine.</li> </ul>

*(table continues overleaf)*

Smith <i>et al</i> (2000)	Context	Experiences, concerns and willingness to participate in decision-making about medicines was explored and compared between patients with the three conditions. Group interviews were arranged via voluntary organisations for each condition in the UK.
	Findings	<ul style="list-style-type: none"> <li>- Patients with schizophrenia had experienced medicines as a way for doctors to modify their behaviour in order to be acceptable in society.</li> <li>- Patients wishing to leave decisions about medicines to doctors still wanted to be informed about positive and negative effects so that they could monitor their treatment.</li> <li>- Information about medicines is used to participate in decisions and challenge doctors.</li> </ul>
Cranney <i>et al</i> (1998)	Context	In an investigation of barriers to implementation of guidelines for hypertension treatment, UK healthy elderly patients' and GPs' perceptions of risks and benefits was addressed. Participants recruited via a GP practice (75 patients) and on a training course (121 GPs). Attitudes to risk with untreated hypertension and ideas about benefit from prescribed medicine were assessed with questionnaires accompanied by visual aids during semi-structured interviews.
	Findings	<ul style="list-style-type: none"> <li>- Most patients overestimate both the risk with untreated hypertension and the benefit from preventive treatment, and accepted treatment based on trusting their doctor.</li> <li>- When provided with information about the clinically proven relative risk reduction, fewer patients accept treatment and more patients mention the risk of side effects.</li> <li>- Communicated ideas about benefit with treatment are rather vague, and based on conceptions of prevention being necessary or helpful in general.</li> </ul>
Leaman and Jackson (2002)	Context	Questionnaire completed by 216 patients from a single GP practice in the UK. A random sample of patients, stratified for age and gender, were asked to state the level of benefit requested for acceptance of a first, second and third medicine for treatment of hypertension. Benefit was represented with fixed levels of NNT(5). Hypothetical scenarios explaining the consequences of a myocardial infarction and some practical aspects of the treatment accompanied the questionnaire, and respondents were asked to answer with only these aspects in mind.
	Findings	<ul style="list-style-type: none"> <li>- Patients request a much higher level of benefit than what has been clinically proven.</li> <li>- Authors mention patients' lack of rationality in making decisions about medicines, leaving decisions to doctors and altered circumstances when facing a real rather than a hypothetical situation as explanations for why so many patients are on treatment for hypertension despite the results in the study.</li> </ul>

*(table continues overleaf)*

Fuller <i>et al</i> (2004)	Context	Older people's attitudes to stroke prevention were examined by presenting probabilities of risks and benefits with warfarin treatment. People aged 66-97 years answered questionnaires about hypothetical scenarios of risk reduction and practical aspects of treatment. The 81 participants were recruited via an elderly medicine outpatient clinic at a large university hospital in the UK.
	Findings	<ul style="list-style-type: none"> <li>- Participants expressed wishes for a guaranteed number of years of disease-free survival in order to engage with medicine-taking.</li> <li>- Experiences of disease in the family and personal health beliefs are influential on the acceptance of treatment.</li> </ul>
Hux and Naylor (1995)	Context	Data on benefit of lipid-lowering medication from a large clinical study was presented in different formats (relative and absolute risk reduction, NNT, average and stratified survival) to 100 participants aged 35-65 recruited from an outpatient setting in Canada. Treatments were presented as free of charge, without side effects and suggested by a doctor in hypothetical scenarios. Participants' preferences and their stated certainty about the decision were recorded in order to investigate how the format of benefit data influences decisions about treatment.
	Findings	<ul style="list-style-type: none"> <li>- Relative risk reduction generated the highest acceptance for treatment, followed by absolute risk reduction.</li> <li>- Stratified survival data was preferred over average numbers.</li> </ul>
Arkell <i>et al</i> (2013)	Context	Experiences, attitudes and expectations about information given prior to starting anti-TNF therapy were assessed in focus group interviews with ten rheumatoid arthritis (RA) patients in the UK. All participants were currently on treatment and purposively sampled to represent different ages, disease duration and activity and anti-TNF agent used. Data was analysed with a phenomenological approach.
	Findings	<ul style="list-style-type: none"> <li>- Patients described a willingness to face increased cancer risk due to treatment if sustained relief from RA symptoms could be achieved.</li> <li>- Fear of disease symptoms and long-term effects influenced the desire to start and stay on anti-TNF medication; side effects were considered secondary.</li> </ul>
Gale <i>et al</i> (2012)	Context	Meta-ethnography of qualitative literature on usage of medication for prevention of cardiovascular disease, seeking to explore variations in behaviour and implications for practice.
	Findings	<ul style="list-style-type: none"> <li>- The context for patients' decisions about medicines goes beyond the clinical setting – social interactions in the personal community, other people's experiences and various sources of information are influential.</li> <li>- Doctors are trusted sources for information about medicines; information from academia, pharmaceutical companies and media is less trusted.</li> </ul>

*(table continues overleaf)*

Sale <i>et al</i> (2011)	Context	A phenomenological study conducted to investigate patients' experiences with the decision to take OP medication after sustaining a fracture. Participants aged over 65 years who had had a fracture in the last five years and were at high risk for having another one were recruited via an OP screening programme in Canada. Two thirds of the 21 patients were currently taking OP medication. Cost for medication was covered by a local drug plan for all participants.
	Findings	<ul style="list-style-type: none"> <li>- A decision to use or not use medicines is often not permanent; patients report they have changed their mind about medicines or might do it later.</li> <li>- The decision to start OP medication is often based on trusting the prescriber's recommendation.</li> <li>- Discussing the decision about medicines with friends or family or searching information elsewhere often resulted in not accepting treatment.</li> </ul>
Adams <i>et al</i> (1997)	Context	Asthma patients' attitudes to prophylactic medication are explored with a patient-centred perspective. In-depth interviews were carried out with 30 participants recruited from a GP practice in Wales. Participants represented different ages, social backgrounds and duration of asthma.
	Findings	<ul style="list-style-type: none"> <li>- Using medication every day is closely linked to the idea of having a disease.</li> <li>- Those patients that accepted the treatment as part of living with asthma still disliked using medicines every day.</li> <li>- Negative views on steroids, associated with illicit use, were overcome by the fact that they are needed by the patient and prescribed by a professional.</li> </ul>
Stack <i>et al</i> (2008)	Context	Patients beliefs about multiple medicines are addressed in interviews with 19 patients diagnosed with cardiovascular disease and type II diabetes. Authors acknowledge that usage of many medicines is associated with poor adherence and self-management in patients. Recruitment was done via two urban GP practices in the UK.
	Findings	<ul style="list-style-type: none"> <li>- Diabetes medicines are seen as necessary, whereas medicines for the management of cardiovascular risk, especially lipid-lowering agents, are given lower status.</li> <li>- The patients that describe a perceived risk for cardiovascular events have experienced heart attacks or strokes among family or friends.</li> </ul>
Marshall <i>et al</i> (2006)	Context	Relations between level of cardiovascular risk, acceptance of treatment and demographic characteristics were investigated quantitatively. Patients without diagnosed cardiovascular disease from GP practices in the UK were invited to participate in coronary risk screening and a research study. Preferences regarding treatment in hypothetical scenarios were recorded from the 181 participants before the screening, and a second interview was conducted afterwards to see whether patients changed their minds when told about their own risk.
	Findings	<ul style="list-style-type: none"> <li>- Patients' preferences are stable over time but vary between individuals.</li> <li>- A difference in acceptance of treatment between patients from different social classes is suggested to be related to ideas about moral obligation to use medicines.</li> </ul>

## Chapter 3

### The public debate about cardiovascular risk

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#### **3.1 Chapter overview: newspaper coverage of an updated clinical guideline**

From researching the influences on patients' understanding of the benefit of risk management medicines, and concluding from my synthesis of the literature that factors both within and outside the medical field contribute to that understanding (see chapter 2), the lay debate about medicines and risk is clearly an important source of knowledge. In this chapter I present an analysis of how CVD risk and risk management medicines were portrayed in UK newspaper articles, and discuss the content and format of messages about health and disease that are available in the press.

#### **3.2 Medicines in the media**

In the scoping conversations with GPs at the start of this project (see appendix A1), the internet and print media were repeatedly mentioned as influential on patients' willingness to accept treatment that targets risk factors for cardiovascular disease (CVD). Newspaper stories and internet forums have also been suggested as playing a part in shaping patients' views, expectations and demands regarding prescribed medicines.[119-122]

With the current availability of information on health-related topics in both traditional and new media, and possibilities for anyone to publish, share and comment, this area is vast and changeable – and therefore challenging to research. However, an opportunity to explore a few aspects related to CVD risk management arose at the time when the UK National Institute for Health and Care Excellence (NICE) released suggestions for an update of the clinical guidance on CVD risk assessment and lipid modification in February 2014 (see figure 3.a).[123] The content provoked a debate in the medical community, and both the dispute and the new guidance were also discussed in public media. The reporting around the extension of treatment with statins to people at lower levels of risk offered an opportunity to research how CVD risk and the benefits and harms from statins were represented in a lay context; i.e. in UK newspapers. Key features in the discussion were the appropriate end-points for assessment of

benefit and harm in a population at low risk.[124-127] Two systematic reviews of side effects attributable to statins [128,129] were published in the month after the suggested updates to the clinical guidance, and they were also widely discussed in the newspapers.

<b>NICE press release:</b> NICE advises much wider use of statins in draft guidance
<ul style="list-style-type: none"> <li>- Doctors are recommended to consider many more people to be at risk for heart disease, stroke or peripheral arterial disease and systematically search for people at risk.</li> <li>- The threshold for starting preventive treatment should be halved from 20% to 10% risk.</li> <li>- The guideline is updated due to new evidence on risk assessment tools and a lower price for statins that makes treatment cost-effective.</li> <li>- CVD causes 1/3 of deaths in the UK; 180.000 cases/year but rates have halved since the 1970's and 1980's.</li> <li>- Before the guideline update, 7 million people in the UK are prescribed statins at a cost of £285 million per year.</li> <li>- CVD disproportionally affects socially deprived people or those with a low income, and the rates are higher in the north of England.</li> </ul>

Figure 3.a Key messages in the updated guideline, as stated in the press release from NICE in February 2014 [130]

### 3.3 Health care policies and the social world

Whilst relations between risk factors and outcomes established within a biomedical model of health and illness guide prescribing, factors in the social world also influence how medicines are used. Contextual and societal factors may facilitate or hinder implementation.[131] From this, it follows that the impact of for example prescribing policies depends not only on their content, but also on how they are received by the people whose health they are to influence. Patients' acceptance or rejection of prescribed medicines is a key determinant of implementation success.[98] Media is one of the factors that have been shown to influence patients' perceptions of the need for medicines – their portrayal of health and medicines are influential on how health services and interventions are used.[132] It should be noted that print and broadcast media have been criticised for shortcomings in the representation of risks and benefits [133] and single-sidedness in their descriptions of medicines' effects.[120]

In relation to the theoretical background for my study, this review of how CVD risk and risk management are described in UK newspapers is informed by the suggestion that the media contributes to the view that health problems can be solved with medicines.[56] As outlined in chapter 1, one aim of this project is to test the concept of pharmaceuticalisation in the context of CVD prevention in UK primary care. This review focuses on descriptions and debate around statins, and seeks to understand them as a source of social influence on patients' understanding of this class of CVD risk management medicines. In addition to considering to what extent the biomedical evidence is correctly presented, my attention is also directed towards which other explanations are offered in relation to CVD risk and how professionals' and patients' accounts are presented.

### **3.4 Statins prescribing as a model of prevention policies**

In the particular case of CVD risk management in UK primary care, statins are a central class of medicines. Simvastatin was the pharmaceutical product with the highest number of items dispensed in 2014 and atorvastatin also make the top 20-list.[134] The proposed (and subsequently adopted) change to the clinical guideline for blood lipid modification entails a lowering of the risk threshold at which people should be offered high-intensity statins treatment from 20% or higher risk for developing CVD within 10 years to 10% or higher risk. As reasons for updating the guidance, NICE states new evidence regarding risk assessment tools and also the price and availability of generic statins.[73]

Together with medications against high blood pressure, statins are at the core of cardiovascular prevention in primary care. For the purpose of this research project; exploring whether prevention policies contribute to polypharmacy and overprescribing, they are therefore a suitable object of study. As the new guideline was motivated with arguments about the evidence around risk assessment, it reflects the current focus on population-level prevention, and the link between lower prices for statins and increased prescribing shows how not only clinical features have a strong influence on primary care practice.

Others have also used the introduction, establishment and extension of treatment with statins as examples to examine influences from the social world on the use of medicines for the purpose of disease prevention. For example, Greene [61] writes about how regulatory changes in the US paved the way for large, industry-sponsored clinical trials of statins between the

1970's and 1990's. Their results were used to change the definition of what a 'normal' cholesterol value was, and a 'desirable' value that made the majority of adults in the US eligible for treatment was introduced into guidelines. Increased testing of blood cholesterol, facilitated by pharmaceutical manufacturers through distribution of screening equipment to surgeries and pharmacies, has been used to expand prescribing in the US and the UK.[60,135] Will and Weiner [136] used the introduction of statins OTC in the UK to examine consumerism and demand for medicines, but found the highest expectations of benefit from this change, in the form of foreseen increased sales, among policy-makers and industry instead of among people wanting to access medicines.

With this analysis of the representation of CVD risk in UK newspapers, I aim to examine how a current prescribing policy is represented to the public. My research question was "What representations of CVD risk, and the benefits and harms of statins in managing that risk, are communicated by UK newspapers?"

### **3.5 Methods**

Qualitative analysis of texts can be done with several different approaches, including content analysis, discourse analysis, narrative analysis and thematic analysis. To allow for both testing of *a-priori* suggestions based on the research question and other emerging findings, I chose to use thematic analysis. This method is flexible and therefore useful across a potentially diverse range of texts such as extracts from newspapers.[137]

#### *3.5.1 Identification of articles*

Articles were identified from a purposive sample of eight national UK broadsheet and tabloid newspapers including their weekday and Sunday editions. For a description of the idea behind purposive sampling, see chapter 4, section 4.4.4. The selection of newspapers was done based on their circulation size and seeking maximum variation in terms of editorial stance and readership,[138] see table 3.1. Included newspapers represent a range from 'serious' to 'tabloid' publications.[139] Local or free newspapers (Metro, Evening Standard) were excluded since they are not available nationally. The time frame for sampling was from February 12<sup>th</sup> to March 31<sup>st</sup> 2014, which was the period when stakeholders could comment to NICE on the draft guideline.



Table 3.1. Sampling framework.

<b>Name of newspaper</b>	<b>Circulation 2014 (weekdays/Sunday)</b>	<b>Readability (Flesch Reading Ease Test)*</b>
The Sun/The Sun on Sunday	2.2M/1.8M	62
Daily Mirror/Sunday Mirror	1.0M/0.9M	57
The Independent/Independent on Sunday	66K/0.1M	50
The Times/The Sunday Times	0.4M/0.8M	49
Daily Telegraph/The Sunday Telegraph	0.5M/0.4M	48
Daily Mail/The Mail on Sunday	1.8M/1.6M	40
The Guardian/The Observer	0.2M/0.2M	33
Financial Times	0.2M/NA	35

\* A readability score higher than 60 represents plain English accessible to 13-15 year-olds; 50-59 represent fairly difficult text accessible to 15-19 year-olds and 30-49 represents difficult text accessible to those educated to a college/university level.

The Lexis®Library database of newspapers was searched in two stages, on March 18<sup>th</sup> (40 hits) and March 31<sup>st</sup> (27 hits) 2014. The same broad search criterion was used in both searches: appearance of the word ‘statins’ in the headline or text. Texts that mentioned statins but did not refer to the updated guideline were excluded, for example letters with personal questions about statins use, comparison between statins and foodstuffs that have an effect on cholesterol, or texts casually referring to statins. Duplicates as well as texts of the type ‘corrections and clarifications’ were also excluded, so that the material for analysis consisted of final versions of published articles.

### *3.5.2 Analysis of articles*

To find answers to the research questions while also looking for indications of other ways to present CVD risk and its management, I used open coding and thematic analysis.[137] As a conceptual framework for the critical examination of articles, I used the applicable aspects of the pharmaceuticalisation framework. It describes influences of the social world, such as health care governance, market forces and the media on the portrayal and use of medicines, and the involvement of pharmaceutical industry in these processes.[56] For the purpose of this analysis,

the changing definitions of health problems, the relations between regulatory bodies and private interests and the influence from media's portrayal of health, illness and medicines were particularly useful.

The analytical process started with a search through the included articles for data that addressed the research question – namely what images of CVD risk and risk management with statins are communicated by newspapers. The search was also open to pick up data that confirmed or challenged the *a-priori* questions, for example by describing the usage of medicines for risk management in novel ways or portraying risk as something different than what is indicated in the clinical guideline. Extracted data were collected in a spreadsheet along with a brief description of what aspect of the research question it related to. An overall assessment of whole articles was also done at this stage, to summarise the context from which each of the data extracts had been taken.

The next step was interpretation of data to establish meaning, guided by the conceptual framework. All data extracts were assessed and given one or more descriptive codes that indicated for example the type of language used, whether it described specific cases or risk management in a population context, if it focused on the guideline, the reports about side effects or the clinical efficacy of statins, and how it described different stakeholders (professionals, academics, pharmaceutical industry or patients) in relation to the new guideline.

As analysis progressed and the list of descriptive codes grew, the codes were grouped together into emerging themes. For each addition of a category to a theme, the included data extracts were compared with other ones in the group, so that each theme described as many aspects as possible of related phenomena but still stayed separate from the other themes.[100] A final adjustment of the themes was done during the writing up of the findings, by critically reviewing them in relation to the research question and the conceptual framework for this study.

After the detailed coding and initial appointment of descriptive categories, I discussed the further interpretation of data and development of themes with Prof Walley and Dr Reeve. Included in the analytical process was also questioning of the trustworthiness of the research methods and the emerging findings – whether the processes of data collection and interpretation were valid with regards to the research question and if the analysis was a useful contribution towards explaining the phenomenon that is being investigated. Informed by the questions suggested by Miles and Huberman,[94] I focused this validation on the authenticity (i.e. do the findings make sense and are they giving a truthful presentation of what is going on), the

transferability (i.e. can the findings and the identified meanings be used in any other context) and the applicability (i.e. do the findings offer any usable knowledge) of the process.

### 3.6 Findings

Sixty-seven texts mentioning statins were identified, of which 42 were excluded according to the previously defined criteria. The distribution of articles between newspapers is displayed in table 3.2.

Table 3.2 Number of articles identified and excluded.

Name of newspaper	Number of articles retrieved	Number of articles excluded
The Sun/The Sun on Sunday	6	4
Daily Mirror/Sunday Mirror	3	2
The Independent/Independent on Sunday	2	2
The Times/The Sunday Times	14	10
Daily Telegraph/The Sunday Telegraph	22	15
Daily Mail/The Mail on Sunday	11	5
The Guardian/The Observer	9	4
Financial Times	0	-
<b>Total</b>	<b>67</b>	<b>42</b>

Twenty-five articles matched the inclusion criterion of referring in some way to the updated guideline. They are displayed in table 3.3 at the end of this chapter. Included pieces consist of editorial material (short items, reports, columns, Q&A sections and readers' contributions) and texts written by external contributors that are medical and academic professionals. In contrast to previous analyses of newspaper articles about medicines,[121,133,140] most of the longer pieces written by journalists contained information about positive as well as negative effects. Some of the external authors took a clear stance in supporting or criticising the proposed new

guideline, focusing either on the anticipated benefits or harms from extended prescribing and also accusing each other of lacking in scientific skills or plainly being wrong.

Amongst the sometimes dramatic accounts of the updated guideline, I identified four themes related to descriptions of CVD risk and its management with statins. These include the *a priori* themes, being descriptions of the nature of risk for CVD and the effects of statins in CVD risk management. The additional emerging themes were the newspapers' roles in helping patients make informed choices about statins and the lack of discussion about social aspects on health.

### *3.6.1 CVD risk is identifiable and measurable*

Articles portrayed the risk of suffering from CVD as dependent on a combination of discreet and identifiable factors: age, sex, smoking, diet, blood pressure and blood cholesterol – the same risk factors that were mentioned by NICE in the press release.[141-146] There was a particularly strong focus on age as a risk factor, and the guideline was said to make “most men over 50 and women over 60” eligible for treatment.[146-149]

The aspect of the updated guideline that considered changes to the assessment of CVD risk was discussed far less extensively than the extension of prescribing. Only two articles [143,144] elaborated on how the risk assessment is done; one of which was a response to a reader's question about how people at risk are identified. Past medical history, age, weight and levels of cholesterol and blood pressure were said to be used by doctors as they come up with a “best guesstimate” of the risk for disease.[143]

Risk was described as something that could and should be controlled by individuals, whether by using medicines to do it in a “clean and effective way”[150] or by people changing habits to make sure they “lost weight, exercised more, ate healthily, stopped smoking and drank in moderation”. [151] Although lifestyle changes were acclaimed in all articles, there were also comments about how difficult they are to sustain; and as most people will not succeed, statins are needed instead.[152]

### *3.6.2 Statins save lives – but they also cause problems*

A range of metaphors illustrated how statins work in CVD risk management. By lowering cholesterol they were said to “reduce the risk”, “protect the heart”, [142] “guard against strokes and heart disease” [144] and “cut heart attacks and strokes”. [145,153] Most articles stated the preventive effects of lowering cholesterol with statins but there were also cases of questioning

it. For example, a doctor referring both to research and to his own experiences of using statins said “high cholesterol has been a scapegoat for too long”.[147]

Possible benefits and harms from statins were also described. The benefits were depicted with reference to the whole population and clinical trials. Statins were said to “save 7000 lives in the UK every year”[148] and the new guideline “will save 2000 lives”[154] and “could prevent 10.000 heart attacks”[141] annually. The benefits were described in an ascertained way, saying that using statins will save lives (or; not using them will cause deaths).[154-157] Hence, the effect of the medication – a reduction of the risk for heart attack and stroke – was illustrated by means of extreme outcome measures.

In contrast to the cohort-based outcome measures for benefits, side effects from statins were illustrated with personal stories from the writers, their patients or other named individuals. Readers get introduced to an elderly lady who “suffered such painful muscle aches (...) that she had to give up the tea dances which were keeping her fit”[158] and a GP that had been forced to “give up badminton, his favourite form of exercise”.[142] There were also accounts of people stopping using statins and feeling “great” or “better than I have in years”.[147,159]

Experts speaking in favour of the guideline were quoted saying that the benefits of treatment “will outweigh any harm”,[141,144,146] citing the small number of side effects reported in clinical trials. Prescribing statins to people at the new, lower risk level “undoubtedly represents a good deal for the British public” according to one author, who thereby summarised the complex issue of risk management into mundane, everyday language while also wording it in a way that take benefits for granted.[141]

However, implementation of the new guideline was also described as “a public health disaster”.[160] Journalists and medical professionals taking a critical stance stressed that people becoming eligible for treatment under the new guideline “are in good health”[160] and “not ill”.[150] They contrasted a lower CVD risk in the population with the possibility of individuals experiencing side effects: “most of the patients do not need the pills, will never benefit from them, and may be harmed by them”.[158] In one of these critical articles the population perspective was instead referred to as “the taxpayers picking up the ever-growing bill” for looking after people with side effects.[160]

The trade-off between benefits and harms that is a central feature of risk management prescribing was addressed in most of the included articles. In describing possible outcomes,

seven of them focused on the positive effects, six on the negative and nine offered a combination of both. Even so, only few examples of straightforward descriptions of the underlying principles for the guideline were described. None of the articles presented any numerical value – absolute or relative risk reduction – indicating the effect of statins for an individual. I also noted an absence of any discussion of the discrepancy between the effect measures of ‘lower risk due to lower blood cholesterol’, which might be achievable for most people treated, and ‘life saved’ that will be achieved only by few. Rather, the frequent picturing of statins as life-saving medicines points towards a conclusion somewhat like ‘lowered cholesterol means survival’. An example is a medical professional who writes that the prescribing of statins to people at the new, lower risk level is required “if we want to stop deaths which seem to come out of the blue”. [141]

One attempt to clarify the balancing of possible benefits and harms from statins was available in *The Times* on March 25<sup>th</sup>, where a medical professional contributed a column illustrated with ‘number needed to treat’ and ‘number needed to harm’. The author also points out that although an alleged 25% reduction of the risk for a heart attack sounds good, even a large proportional decrease will still not have a very big protective impact if the risk is low to start with. This is put in relation to a remark about possible negative effects: “The downsides remain the same whatever your underlying risk, so there comes a point where the drugs are likely to do more harm than good.” [151]

Whilst some articles presented evidence for statins’ benefits largely as described by NICE in the press release (see figure 3.a) or stated brief conclusions from the two reports about side effects, others offered a more discursive debate of the topic. Short, single-sided reports appeared in the newspapers with the highest readability. Stronger opinions and elaborate discussions were published in papers using more difficult language. Some of these were written by medical professionals either supporting the message from NICE [141] or criticising the guideline based on a combination of personal experience and medical evidence. [147,160] The longer articles written by journalists discussed the guideline in the light of the ongoing scientific controversy over benefits and harms from extended treatment. [142,149,150,155]

### *3.6.3 Making an informed choice*

One of the emerging themes stems from the observation that in addition to reporting about the scientific disseminations, the newspaper articles also went on to consider the implications for their readers’ decisions about using statins. Some articles described the guideline in terms that

indicate it being a rule – people “will be urged”, “will be told to take”, “should be taking” or even “will be put on” statins.[144,150,154] A reader of The Sun had interpreted the prescribing guidance as “A health watchdog is trying 2 get the healthy addicted 2 statins with dangerous side effects cos they r cheap”.[161] However, the majority of articles were less prescriptive in interpreting what the new clinical guidance means, saying people would be offered the tablets.[145,153,162]

In the face of possibly being considered for a statins prescription, the newspapers stress the importance of making a personal decision about whether to use statins or not. Some articles suggested that this individual interpretation of risk and benefit should be done together with one’s own doctor, who could provide “a discussion, weighing up the risks and benefits” and “trustworthy advice (...) support and continuity of care”.[146,152,158]

By using headlines such as “The truth about side effects”[142] and “The risks you must know about” [151] newspaper articles also actively took on the role of helping patients make decisions. A direct and personal language was used in these texts. One journalist opened an article discussing benefits and harms with “Should I, or shouldn’t I take a statin?”[151] and a medical professional concluded his piece with “whatever NICE says, you won’t need those statins at all”.[160]

A final possible source of information for readers’ decisions about medicines is the various experts that were cited in articles or appear as authors. In addition to the content of statements about the possible benefits or harms of statins and the impact of the guideline update on public health (which have been referred to above), the presentation of the contributing medical professionals might influence how people perceive the message about statins. Experts that expressed their support for extended prescribing were described primarily as academics, whereas those that criticise the lower threshold were portrayed as clinicians; GPs or specialists that speak from experience of their own or their patients’ use of statins. In describing the row between academics over the data that underpins the new guidance – both its quality and the access for independent parties to evaluate it – additional experts were cited. This debate highlights risk management prescribing on a more conceptual level, by discussing the types of data and knowledge that are created in different types of investigations. Some information that could potentially guide people’s decisions was provided, as clinical trials were contrasted with “real world data”. [162] However, alongside the discussion of strengths and weaknesses of

different approaches were accusations of inadequate research practice and fear-mongering [142,149,155-157] which might divert readers' attention.

#### *3.6.4 CVD risk management is a medical issue*

The fourth theme arises from the realisation that the link between social deprivation and CVD was largely absent from the newspapers' reports about risk management and statins. Although this association, along with an explicit example mentioning the higher prevalence of CVD in the north of England, was included in the epidemiological information in NICE's press release (see figure 3.a), only one article picked it up. The Daily Telegraph mentioned the link between CVD and poverty in a critical examination of the new guideline.[158] It was suggested that "proper public health policy" should target lifestyle and poverty rather than turn to overly generous prescribing of medicines, albeit without any suggestions of how this could be done.

On the contrary, information that was provided about CVD places it in an epidemiological context with references to it as being "Britains biggest killer"[146] and causing one third of all deaths in the UK. [145,162] Although the risk for CVD was described as largely related to lifestyle, medical approaches were put forward as the way to achieve change – whether by prescribing statins or using other methods: "GPs will hand out pills instead of tackling the root causes of heart attacks and strokes".[162] The medical framing is strengthened by frequent references to general practice as the stakeholder that will be responsible for implementing the guidance. GPs will have to "do much more to identify patients between 40 and 74"[144] and will also have to withstand an increased burden of visits due to side effects.[160]

The lack of alternative perspectives on this systems level stood in contrast to the critical descriptions of the new guideline as promoting medicalisation and being influenced by commercial interests. One journalist asked if "we really want our highly educated GPs to act merely as robotic functionaries of the public health" when "treating people as a undifferentiated mass".[158] It was said the guideline "is going to benefit the pharmaceutical industry more than patients"[145] since NICE "seems to be siding heavily with the drug companies".[160]



### 3.7 Discussion

For the consideration of how this analysis contributes to my investigation of patients' understanding of prescribing for prevention of CVD, this discussion will focus on how the newspapers portray cardiovascular health and statins to their readers.

The co-existence of positive and negative effects from statins within the same articles differs from the findings by Prosser and Clayson, who found that newspaper articles often were dominated by one of two themes; that the drug in question was described in either solely positive or negative words.[121] This is a positive finding with regards to the topic of risk management prescribing, as more balanced or complex accounts of medicines' effects might help to give a more comprehensive and realistic representation of risk management from both a clinical and a patient perspective.

#### *3.7.1 Individuals' decisions about risk management*

My analysis revealed that CVD risk is portrayed as something that is possible for people to control by taking action, whether by using medicines or changing lifestyle. The risk assessment process is not elaborated on to any particular extent; although there were indications of a measured risk score being a 'guesstimate' and dependent on the method used, the very concept of assessing risk in asymptomatic, middle-aged people was not questioned. Thus, the newspapers' portrayal of CVD risk as a matter that deserves medical attention is in line with current national strategies for prevention of ill health. So are the indications that risk is controllable, and the concurrent advice that emphasises individual responsibility for cardiovascular health by combining information about early medical intervention with messages about the need to stop smoking, eat healthily and exercise.[65]

In addition to the image of CVD risk as being closely linked to personal habits, the usage of medicines to manage the risk was also described as an issue for the individual to make decisions about. As part of their characteristic "personalisation" of news items, some of the newspapers introduced conflict and experiences alongside the scientific messages communicated from NICE and researchers. The most apparent example of the focus on the individual is the personal stories about side effects. Here it should be noted that the nature of risk management prescribing – where treatment success is an avoided episode, that is, a 'non-event' – makes it difficult to produce equally personal stories of good experiences from statins. However, whereas I found several articles where medical professionals who criticised the new guidance

were writing about their own problems with side effects, there were no examples of those supporting extended prescribing of statins saying how they themselves used and appreciated the medication.

All the newspaper articles illustrated the benefits from statins using national figures for morbidity and mortality from CVD – the same outcome measures that were used by NICE in the press release about the updated guidance. The protective effect from statins was said to be due to lowering of cholesterol in the blood, but figures showing the risk reduction attributable to statins – either in absolute or relative numbers – were not mentioned anywhere. There was no straightforward discussion of the discrepancy between the effect measures ‘lowered risk due to lowered blood cholesterol’ that might be achievable for most people treated and ‘life saved’ that will be achieved by only a few. Rather, the frequent picturing of statins as life-saving medicines points towards CVD risk management as a matter of life and death, with an inference somewhat like ‘all that lower their risk will survive’.

Thus, my analysis points to a dualism in how the concept of benefit from medicines used for risk management is communicated: as a way to lower population-level morbidity and mortality and as an individually achievable protection against an equally individual CVD risk. What is implied by the professionals behind the guideline differs from the assumptions that might arise from newspapers’ reports about it. The potential of thousands of lives saved might help to provide patients with a rationale for wider prescribing, but falls short of the individualised benefits hinted at in the newspapers’ interpretation of risk management.

A novel theme that emerged during the analysis was how the newspapers stressed the importance of making a personal choice about whether to use statins or not. This again points to individuals’ responsibilities in balancing risk, benefits and harms, and also highlights the different sources of information that are presented. As suggested by Gale and colleagues,[115] people are often confident that their GP can interpret scientific information about CVD for them, whereas for example academics are less trusted sources. Alongside the focus on experiences from using statins, advice from a family doctor was indeed put forward as an important resource in decision-making. No corresponding advice was given by the newspapers regarding the value of trusting academic researchers (apart from when they appeared as authors and stressed it themselves). Moreover, the difference in how quoted professionals were portrayed in the newspaper articles may influence how their advice is perceived. Those speaking of their own experience of statins as a reason for their critique of the guideline were

described in terms of their clinical work, while those citing clinical trial data in support of extended prescribing were presented as academics.

Overall, the implications of the guideline on people's decisions about CVR risk management is presented as a discussion about statins – the risk assessment process was not given much attention. In contrast to the perceived certainty about risk, medication introduces uncertainty. Two parallel accounts of statins are made available to people by the newspapers: they are both life-saving and sources of problems in the form of side effects.

### *3.7.2 Risk management as a systems issue*

Alongside presentations of the use of statins as an issue for individuals to decide upon, the newspapers also discussed the new guideline in the context of cohort strategies for disease prevention. In this sense, a majority of articles contrasted the potential public health gains with critique against possible motives behind extended use of pharmaceuticals.

The reliability of data underpinning the new guidance was questioned on the basis of limited access for researchers to evaluate it. So was the applicability of clinical trial data produced by pharmaceutical companies on patients in clinical practice and daily life. Representatives for the research team that showed benefit from extended prescribing of statins defend their conclusions with regards to large amounts of data, the low cost and relative safety of statins. As indicated by Fontana and colleagues [88] this might still not reflect people's perception of what is an acceptable balance between benefit and harm to consider using statins. The debate in the newspapers over the incidence of side effects highlights a difference in priorities between the producers of guidelines and the people whose acceptance their implementation relies on: statins are not primarily criticised for their lack of effect but for the potential for side effects. From the perspective of patients' understanding of CVD risk management, this points to a weakness in the dominance of clinical trials for investigating the effect of medicines, as trials are usually designed to show a certain efficacy but do not capture other aspects. Previous critical examinations of the reliance on private interests for the production of data about the use of medicines have also focused on the consequences in terms of overprescribing of products with questionable efficacy.[45,62] However, my analysis suggests that the UK newspapers have a different focus when reporting about medicines.

An emerging theme in my analysis was the apparent unwillingness of newspapers to discuss the role of deprivation for the prevalence of CVD. Overall, the newspapers expressed criticism

towards increased prescribing of statins to tackle CVD but they failed to address possible systemic causes of ill health. References to social determinants of health [163] or community-wide strategies [164] to limit the harm from foods, alcohol and tobacco were absent from the articles.

Taken together, the newspapers frame both personal and public health aspects of CVD in a medical rather than a social context. This observation links directly to the theoretical framework that informed my analysis: media contributes to the societal understanding of health matters and to expectations of pharmaceutical interventions as a way of maintaining health.[56] Although the newspapers may question particular medicines, as was the case with statins in this particular study, their framing of CVD risk and its management in a medical and pharmaceutical context instead of for example a social one could contribute to increased prescribing.

### *3.7.3 A patient decision aid*

The publication by NICE of a patient decision aid for statins [165] in November 2014 (after this review was finished) adds some aspects to my findings. Firstly, it confirms that the initiation of statins in primary prevention of CVD is indeed far from straightforward and requires careful balancing of potential risk, benefit and harm. Secondly, it contributes to framing the decision as one that the patient does – although guided by a medical professional, the emphasis is on the individual's involvement.

The decision aid spells out that (for most people) lifestyle changes should be carried out before considering taking a statin to reduce one's risk of heart disease. Such changes are also presented in a medical context, as the guidance refers to the health care practitioner for support. In terms of describing interventions to manage risk, they are centered on atorvastatin, which is the recommended first-line treatment for lipid modification in prevention of CVD.[123] The decision aid also emphasizes that all people who lower their risk will not avoid disease, and that it is not possible to predict risk perfectly. It gives graphic presentations of different levels of risk and the possible impact of treatment with a statin. Data for the incidence of side effects are presented, and patients are given a rating tool to summarise the importance of various aspects of risk management from their own point of view.

In relation to my findings regarding the public debate about CVD risk management and statins, this decision tool brings together many important aspects. However, it still frames CVD risk

as a medical issue with medical solutions, and there is no acknowledgement of where the evidence for benefit from statins at various risk levels, or the data on side effects, comes from. The criticism voiced in newspaper articles, situated in a wider critique against the lack of transparency in clinical trials [166,167] is not addressed by NICE.

#### *3.7.4 Validity of findings*

This investigation of newspapers' descriptions of cardiovascular risk and usefulness of statins encompasses only a small part of the media portrayal of medicines at a particularly controversial point in time. However, it provided an opportunity to assess the media representation of a guideline that might expand the usage of medicines in the UK and represents the type of prescribing that is the topic for this thesis. Indications of newspapers taking on the role of helping patients make decisions about health and medicines justifies its place in my examination of influences on patients' understanding of CVD risk management.

The analysis presented here draws on a purposive selection of newspapers representing a variety of editorial and readership stances. A limitation of my analysis is introduced by the way I approached this particular type of literature. When surveying the representation of CVD risk and statins in the newspapers, I sought to include publications representing different readerships. The resulting dataset thus contained stories aimed at various segments of the population – groups for which, perhaps, CVD risk has different impact in terms of both epidemiology and views on its meaning. Alternative ways to explore the media messages about statins could have focused on a certain type of newspapers and how they present CVD risk to a particular segment of the population, e.g. the “red tops” or those with a middle-class readership.

The representation of CVD risk and statins that emerges from my analysis builds on critical reading of the texts both as whole stories and as compilations of detailed information, and construction of themes from the data. Informed by theoretical descriptions of how media contribute to the popular image that all health problems can be solved with medicines, my attention was directed towards accounts that would support or challenge that.

The included articles discussed many different aspects of CVD risk management and statins, including conflicting ideas about using medicines to individuals and populations, and thus my analysis gives a comprehensive overview of how a scientific debate may be represented in a lay context.

However, the richness and density of information in newspaper stories presented a methodological challenge in this study. Many of the included articles were quite long reports and heterogeneous in terms of arguments and voices; the accounts of journalists, experts (of opposing opinions) and ‘ordinary people’ were weaved together throughout the texts. As the analysis progressed from coding to categorising, I started to question the open coding approach since each data extract contained so much information that it was difficult to convey all the meaning in them. To resolve this, a stricter coding method based on quantification of pre-defined concepts could perhaps have been helpful – although at the detriment of less depth in the analysis. Another approach that might have captured the complexity and the multiple levels of storytelling in the longer articles would be narrative analysis. My strategy for maintaining focus in the categorising of data despite these challenges was to use the research question as a filter, and remind myself to leave out data that did not relate directly to it.

An alternative way of studying the media representation of CVD risk and statins would be to follow the development of stories in one or a few newspapers over time. Given the many conflicting accounts presented in the articles, this approach could add to the understanding of how patients might get confused by the debate over changing prescribing guidelines.

These reservations regarding the best method for analysis have consequences for the authenticity of my findings, that is, their ability to fully represent the included stories and contexts. A narrative or quantitative approach would probably have produced rather different accounts of the rich sample. Nevertheless, with regards to my research question and in the wider context of this thesis, the findings do contribute a valuable and coherent interpretation of the portrayal of CVD in UK newspapers.

In terms of transferability – whether the findings and their meaning also say anything about other medicines, health issues and interventions – the themes could apply to other clinical fields and discourses about health promotion, since they describe processes that are similar throughout preventive health work and risk management prescribing. One example of applicability of my findings is the strong focus on individual responsibility, views and experiences in health care which resonates with both current health policy and social trends. It offers useful knowledge for communications around disease prevention and health promotion, by showing how different messages are shaped when they reach the public debate. The newspapers’ portrayal of CVD risk in an almost exclusively medical context also raises the question about the development of public health research.

### **3.8 Conclusions**

This analysis of newspapers' accounts of an updated clinical guideline provides insights into an important aspect of strategies for disease prevention, namely how they might be represented in the social world and thereby contribute to patients' understanding. In this study, I have seen how two parallel descriptions of CVD risk management can exist side by side; one building on personal responsibility, decisions and experiences and one driven by data and policies.

The message from NICE focusing on population-level outcomes was delivered alongside individual perspectives on possible benefits and harms with statins when published by the newspapers. Personal experiences of statins use are contrasted with experts' data about the effects, and the newspapers fail to reconcile the potential conflict between outcomes on the individual and population levels. Moreover, the newspapers discussed the motives behind the new guideline against the background of limited independent evaluation of data.

The newspapers' presentation of CVD risk as something measurable and controllable supports the message in national policies for disease prevention. Personal responsibility for health and disease prevention was put forward in the articles, strengthening the individual focus while leaving out structural factors influencing health. Most of the discussion focused on arguments for and against the extended prescribing and use of statins, and did not elaborate on the CVD risk itself. As I now turn to the empirical part of this research project, I aim to find out how patients understand both the diagnosed risk and the medicines that are prescribed against it.

Table 3.3 Articles included in the analysis, presented in chronological order.

<b>Newspaper</b>	<b>Date</b>	<b>Headline</b>	<b>Type of text</b>
Daily Mirror	12-02-14	Another 5M in line for statins boost	Editorial; news
Daily Mail	12-02-14	Millions more to be prescribed daily statin	Editorial; reporting the guideline update
The Guardian	12-02-14	Nice recommends statins for millions more NHS patients: 10% risk of cardiovascular disease deemed enough: Critics suggest side effects will outweigh benefits	Editorial; reporting the guideline update
The Daily Telegraph	12-02-14	Statins to be given to one in four adults; Mass-medication is backed by evidence	Editorial; reporting the guideline update
The Times	12-02-14	Millions more qualify for drugs to cut heart disease	Editorial; reporting the guideline update
Daily Mail	13-02-14	The great statins divide	Medical professional's contribution; critical to the new guideline
Daily Mail	13-02-14	Statins are cheap and effective way of avoiding 10,000 heart attacks and strokes a year, claims top academic	Medical professional's contribution; supportive of the new guideline
The Daily Telegraph	13-02-14	Mass medication has serious side effects; The advice on statins is part of a medical trend that treats populations rather than people	Editorial; opinion/column about the guideline update
The Daily Telegraph	15-02-14	Why we're going to keep taking the tablets; the health agency with the twee acronym is guaranteed to get our blood pressure rising	Editorial; opinion/column about the guideline update
Daily Mail	17-02-14	Ask the doctor	Medical professional's contribution; column
The Sun	18-02-14	The healthometer	Editorial; reporting the guideline update
The Sun	18-02-14	TXT US	Readers' contributions
Daily Mail	18-02-14	Why do so many GPs say they won't take statins	Editorial; focusing on the article showing statins do not cause side effects



The Guardian	22-02-14	Doctors' doubts over statins may be putting lives at risk	Editorial; focusing on the argument between academics
The Guardian	22-02-14	Statins-for-all debate becomes a prescription for big medical row: Doctors at odds over advice that taking anti-cholesterol pills should become the norm	Editorial; summarising the guideline update and the argument over side effects
The Guardian	24-02-14	The drugs don't work: The claims being made for statins are overblown	Medical professional's contribution; critical to the new guideline
Daily Mail	24-02-14	Doctors' fear over statins are putting lives at risk	Editorial; focusing on the argument between academics
The Times	25-02-14	QA (readers' contributions)	Readers' contributions
The Daily Telegraph	03-03-14	Doctors warn over side effects of statins	Editorial; reporting the guideline update
The Guardian	13-03-14	Statin side effects minimal, study finds	Editorial; reporting the guideline update
The Daily Telegraph	13-03-14	Statins 'have no side effects'	Editorial; reporting the guideline update
The Daily Telegraph	22-03-14	Statins scaremongering will cost lives, expert warns	Editorial; focusing on the argument between academics
The Daily Telegraph	24-03-14	Why I've ditched my anti-cholesterol drugs for good; As experts clash over proposals that millions more take statins to prevent heart disease and stroke, vascular surgeon says he has never felt better	Medical professional's contribution; critical to the new guideline
The Times	25-03-14	Statins could save your life but these are the risks you must know about	Medical professional's contribution; critical to the new guideline
The Times	30-03-14	Millions to get statins despite missing data	Editorial; focusing on the argument between academics

## Chapter 4

### Empirical research methods

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#### **4.1 Chapter overview: choosing research methods**

This chapter describes the methodological choices and the methods used in my empirical study. It explains the choice of research design and outlines the principles of recruitment of research participants, how data collection was done, how the data was analysed and how I will examine the trustworthiness of my findings.

In this empirical part of my study, I return to the research problem that was formulated in chapter 1. Here, I will explore patients' understanding of cardiovascular risk management and how it can add to a more comprehensive characterisation of polypharmacy. So far, I have examined influences on patients' views of medicines through the critical examination of two published datasets: the academic literature on patients' expectations of medicines and the lay press portrayal of CVD risk and risk management (see chapter 2 and 3, respectively). The findings from those studies raised a number of ideas that I now seek to explore further through empirical investigation. Firstly, I want to find out more about how people make sense of the asymptomatic 'condition' of being at risk for CVD, and especially how that understanding shapes decisions about using medicines (or not) to manage the risk. Secondly, I want to find examples of how people picture the possible benefits from medicines, for example if and how expectations of personal gains are negotiated with proposed outcomes on the population level. Thirdly, I want to see which sources of information people draw on when making decisions about CVD risk management and evaluating medicines. The research question I am asking is: "How do patients conceptualise CVD risk management with medicines?"

#### **4.2 Defining a conceptual framework**

As pointed out by Miles and Huberman,[94] research does not take place in a vacuum. Ideas and knowledge held by individual researchers and the wider community shape the questions we ask when designing studies and the way data are collected and analysed to create new knowledge. Identifying these concepts clarifies important relations and sources of information

for a particular study – they form a conceptual framework of key factors and associations to be studied. It also allows for critical examination of the research process and the findings.

The conceptual framework for my study includes the ideas outlined in the theoretical background given in chapter 1, section 1.3; the pharmaceuticalisation critique [46,47,54,56] and the acknowledgement of patients’ practices, experiences and expertise as influential in their own use of medicines.[41] The main components of each concept are shown in table 4.1, and discussed further below.

Table 4.1 Components of my conceptual framework; aspects of the pharmaceuticalisation critique and patients’ agency in medicine-taking.

<b>Conceptual framework component</b>	<b>How it might be perceived in my study</b>
<b>Pharmaceuticalisation</b>	
New or changed definitions of health problems suggest that more conditions should be treated with medicines	How patients might understand the condition of being at risk for CVD, and the role of medicines in treating it
The medicines market is subject to changes that gives the pharmaceutical industry greater influence on the production and dissemination of information about medicines	Patients thoughts about the scientific background for CVD risk management
Media portrayal of health and disease supports the notion that all health problems can be solved with medicines	How information from the social world might be used to understand medicines
Increased use of medicines is presented as medical progress; new products and extended prescribing are said to fulfil health needs and pharmaceutical development is communicated as helping the sick	Informing patients’ views on the increased prescribing for primary prevention of CVD
<b>Patients’ agency in medicine-taking</b>	
Personal goals, experience, priorities and ideas of health and illness as well as notions of morality and responsibility influence how medicines are viewed and used	How CVD risk management medicines fit in with patients’ views of their own health
Choices to take or reject medicines are not merely following or not following instructions based on biomedical aspects of health, but also represent active actions based on personal understanding of prescribed medicines	Many different types of knowledge and expertise might be available from patients

First, as described in chapter 1 (see section 1.3.3), is the theoretical work describing the concept of pharmaceuticalisation.[54,56] It outlines how circumstances in the social world influences the way in which medicines are prescribed and used. Among other things, this body of research indicates that the current model for producing and applying knowledge about the use of medicines and their possible benefit and harm is a cause for concern, through the potential to create iatrogenic effects in health care. Pharmaceuticalisation theorists propose that biomedical arguments are used in health care policy and practice to justify the need for pharmaceutical intervention. The dominance of a positivist scientific paradigm and the increasing influence from pharmaceutical companies over the available knowledge about medicines shapes the discourse around disease and treatment.[45,55,168]. Since most usage of medicines takes place in more complex, real-life situations there are growing concerns over the consequences of the current system.[35] This component of the conceptual framework acknowledges that the type of knowledge about medicines that is made available, and how it is presented, will have an impact on how medicines are used.

The second component of the conceptual framework for this study frames the objectives of the two examinations of literature (see chapters 2 and 3), namely the recognition of patients' own experience-based expertise in using health care services and medicines. Patients' expertise is often different from the knowledge held by professionals, as it includes things like how to negotiate medicine-taking with social roles and obligations or how to balance effects from medicines with illness symptoms in the context of everyday life.[41] Yet it has the potential to influence health outcomes, since perceptions about both medicines and conditions influence how people choose to engage with treatment.[39,102] As described in chapter 2, patients' views of medicines are dynamic and encompass dimensions that fall both within and outside a biomedical description. The conceptual framework for my empirical study therefore recognises social discourses on health, disease, illness and treatment [42,169], lay understanding and application or rejection of scientific knowledge [64,98] and prescriber-patient relations [170,171] as influential on how medicines are used. In relation to this particular study, the range of practices and influences that potentially surround people's use of medicines prescribed to manage a CVD risk condition indicates that the biomedical model is only one of many possible descriptions.

Together, the two parts of my conceptual framework outline that I am exploring patients' understanding of CVD risk management medicines with an aim to explicitly include experiential as well as societal representations of health and medicines.

### 4.3 Methodological approach

My conceptual framework thus describes a need to recognise that patients' understanding of risk management may be different from the current, biomedical view that informs present prescribing policy and practice. This has implications for the ontological and epistemological approaches in the research, for which a background was outlined in chapter 1, section 1.5. Ontology refers to the understanding of what or how the world 'is', and from that follows an epistemological perspective of what constitutes knowledge about the world. Applied to my study, this describes what CVD risk and medicines are, and what 'counts' as valid knowledge about them. The knowledge I seek to produce in this study includes more perspectives than the biomedical, and the theoretical background that informed my research approach highlights for example patients' experiences and practices and changes in the social world as influential on how medicines are used. In order to allow for more than one possible definition of CVD risk and medicines, and let multiple types of knowledge add to the understanding about them, I adopted a critical realist view in my research.

Applied to my study, a critical realist perspective means that CVD risk exists not only by its biomedical definition; the associations between blood pressure, cholesterol and incidence of acute events. It is also present in the form of people's views of what causes risk, how to act to manage it and which sources of information to trust for guidance. Similarly, CVD risk management medicines are not only represented by their effects on physiological processes and population mortality, but also by the moral aspects and values that people attach to them.

As mentioned above, the ontological view in research informs the epistemological perspective; what is regarded as knowledge about the topic. This has implications for the methodology for creating knowledge – in which forms it is available and how it can be gathered. Kvale and Brinkmann [172] use the examples of a miner and a traveller to illustrate different types of knowledge production, where the former looks for pre-established concepts that can be 'dug out', and the latter creates and adjusts the knowledge in interaction with research participants 'along the way'.

A study informed by a biomedical model of health might be designed to identify and quantify pre-established facts about medicines and risk in patients' accounts, for example by using a survey to check what people know about heart disease or how often they experience a particular type of side effect. In contrast, in this study designed to form new theoretical understanding of a phenomenon beyond a biomedical description, the possible knowledge about what CVD risk

and medicines are, and how they might be related to health and illness, is not defined beforehand. Instead, knowledge will be generated as a result of questions, answers and interpretations throughout a research process that aims to produce a rich understanding of the topic. This view of knowledge has implications for my choice of research methods, which are described below.

#### **4.4 Recruitment and sampling of research participants**

The recruitment of participants depends on the research topic and question, the conceptual framework for the study and also practical aspects like time, budget and experience of the researcher.[94,173] In this study, recruitment and sampling were planned using Miles and Huberman's and Lincoln and Guba's advice for purposive and maximum variation sampling.[94,96] This choice reflects the study aim of exploring more understandings of CVD risk management than what fits into the biomedical definition of it. By striving for variation between my participants, I aimed at capturing as many aspects as possible of patients' views and experiences. However, for practical reasons all participants were recruited in Liverpool.

Ethical approval for the interview study was sought prior to any contact with research participants. It was granted by NRES NW, Haydock; reference number 13/NW/0387 on June 28, 2013 (see appendix A3).

##### *4.4.1 Participant population*

This study is concerned with patients' ideas about the medicines that are prescribed to them for primary or secondary cardiovascular risk management. Since I was interested in long-term risk management rather than acute interventions, and such prescribing and monitoring is mainly done by GPs, I recruited participants to the study among patients listed with GP practices.

Findings in the study of influences on patients' expectations of medicines (see chapter 2) indicate that experiences of ill health and medicines' effects over time are taken into account as patients develop their understanding of conditions. Therefore, I anticipated possible differences between how patients with little or no experience of ill health view risk management medicines compared to those that have conditions that impact on their daily life. Calnan [42] even suggests that people only learn about medical care through personal or vicarious experience of it. Therefore, previous experiences of ill health could be influential so

that people at high and low risk might reason differently about benefits from prescribed medicines. Information about treatments given to the patient by doctors and other health care professionals might also differ depending on the level of CVD risk, and including patients at both low and high risk could therefore give examples of different types of communication about risk.

#### *4.4.2 Invitation to GP practices*

An invitation to participate in the research study by recruiting patients for interviews was sent to 32 GP practices in Liverpool, a city in Northwest England with areas of both high and lower socioeconomic deprivation. Practices from across the city were invited, to allow for a purposive sample across areas of different socioeconomic status. The stratification of socioeconomic status was done using the Deprivation mapper published by the UK Department for Communities and Local Government's official website for local data; <http://opendatacommunities.org/showcase/deprivation>, which displays deprivation by deciles (with decile 1 representing the most deprived and 10 the least deprived areas).[174] Invitations were sent by post to practice managers and followed up with phone calls. Initially, only one practice in a decile 4 area with an uptake of patients from deciles 3 to 8 agreed to participate. Fourteen other practices were reached by phone or email but declined due to time constraints, and the rest did not respond in any way. Personal contacts by myself and my supervisors led to two more practices, situated in decile 1 areas in different parts of Liverpool, agreeing to recruit patients.

#### *4.4.3 Identification and recruitment of patients*

Inclusion and exclusion criteria in the searches were chosen to identify patients at low and high risk for CVD, while also being feasible in terms of doing the database searches. For a discussion of the limitations of my search strategy, see chapter 8, section 8.3. The eligibility criteria are displayed in table 4.2. The combination of a low and a high risk group aimed at recruiting participants with asymptomatic CVD risk (such as the presence of one or more risk factors) as well as people with symptomatic heart conditions. All searches for eligible patients among the practice population were done by practice managers and/or staff members responsible for databases.

Table 4.2 Inclusion and exclusion criteria for the interview study.

		Criterion	Explanation
Low risk	Eligibility	Age 40-74 years	The age range for NHS Health Check; a screening programme for heart disease, stroke, kidney disease, type II diabetes and dementia which is offered to all adults in England without pre-existing conditions
		10 year CVD risk $\geq 20\%$ *	Threshold for primary prevention of CVD to be initiated, according to NICE guidelines for lipid modification (CG67)** and hypertension (CG127)
		Prescribed CVD risk management medication within the last 6 months	Including anti-hypertensives (calcium-channel blockers, diuretics, beta-blockers, ACE-inhibitors and angiotensin II-receptor antagonists) and statins
	Exclusion	Diagnosed with ischaemic heart disease, atrial fibrillation, stroke, heart failure or diabetes	No previous symptomatic heart condition
High risk	Eligibility	Age 18 years or older	Any adult could participate
		In the QOF register of heart failure patients	Including NYHA classes I-IV, acute and congestive heart failure, left and right ventricular failure
	Exclusion	Myocardial infarction <12 months ago	Patients needed to be stable on medication
All patients	Overall exclusion criteria	Not on end-of-life care	Not ethically justifiable to include people in research when they are unlikely to benefit from it
		Not in residential care	Having medications dispensed, and also ethically questionable (as above)
		Under 18 years old	Only adults were eligible to take part
		Unable to give consent	Informed consent is a prerequisite for partaking in research
		Unable to speak or understand English	Practical reasons
		Deemed unsuitable to participate by GP	Practical and ethical reasons

\* A person is considered at 20% or higher risk for having a heart attack or stroke in the next 10 years.

\*\* The threshold for lipid modification has since changed.



Low risk patients were identified in the age group 40-74 years by using functions in the practices' database which picked up all patients that had been diagnosed as 'at 20% or greater risk for CVD in the next 10 years' and had been prescribed medication to manage CVD risk within the previous six months. The medicines that were used as search criteria were various types of anti-hypertensives (calcium-channel blockers, diuretics, beta-blockers, ACE-inhibitors and angiotensin II-receptor antagonists) and statins. In some practices the search function was called "10 year CVD risk – Framingham", and in some "QRISK2". Patients diagnosed with ischaemic heart disease, arterial fibrillation, stroke or heart failure were excluded in this search, in an aim to reach patients with little or no experience of symptomatic CVD.

High risk patients were identified as adults on the practice's Quality Outcomes Framework [175] register of heart failure patients. Here, the aim was to reach participants living with symptomatic CVD. To ensure that participants had some experience of using risk management medicines, anyone that had had a myocardial infarction in the last 12 months was excluded.

From the database searches, a list of patient names was put together for partner GPs at the practice to review and from personal knowledge identify anyone that met the exclusion criteria. Since the database searches returned more patients than I planned to recruit from each practice, the list of names was condensed by the person who did the search for me. This was done by hand but according to a principle; selecting for example every third name or the first ten on each page.

The condensed list of these was reviewed by partner GPs at the practice to identify anyone that met the exclusion criteria. These were: living in residential care, being in Gold Standards Framework or other palliative care, inability to give informed consent or participate in an interview in English or deemed unsuitable to participate in an interview study for any other reason. People in palliative care were excluded on the basis that their views on health risks and possible harm and benefit from medicines might be heavily influenced by their terminal condition, and the research undertaken here is unlikely to benefit them in a way that would justify taking up their time. Similarly, people in residential care might be frail enough to make it questionable if they would benefit from the research. Care home dwellers' relation to medicines might also be different from that of independently living people due to the circumstance that they do not entirely decide for themselves about how to use medicines. Since the interviews needed to be conducted in English and research cannot be undertaken without

the participants' informed consent, anyone who did not meet these criteria had to be excluded. The final exclusion criterion was applied so that GPs could use their personal knowledge of patients to avoid anyone not suitable for participating in the study being contacted by the researcher. The remaining patients were invited to join the study.

An invitation letter (appendix A4) was sent to 300 eligible patients from the practices. Along with the letter was a participant information leaflet (appendix A5), a consent form (appendix A6) outlining the details of anonymity and data protection and specifying that the interview would be recorded, and a questionnaire (appendix A7) asking about contact details, age, gender, number of medicines, physical and mental wellbeing, current medical problems and duration of any heart problems. All invitation material was approved by the Research Ethics Committee. Twenty eight patients replied stating an interest to participate in the study.

#### *4.4.4 Selection of participants*

A purposive sampling of patients was done among those that expressed their interest to participate in the study. The sampling frame is available in appendix A8. When selecting participants, I followed the principles of sampling by maximum variation.[94,96] This is a non-random method that seeks to produce a sample in which the investigated phenomenon can be explored from as many different angles as possible, within a group of participants where it is likely to occur. Within the sample, each case represents its' own unique and distinct relation to the studied phenomenon, so that rich descriptions can be collected. It also offers a possibility to look for shared features or central aspects of the studied topic to be identified across different types of accounts.[176]

Categories in the sampling frame [94] were: gender (male or female), age (18-40, 41-60, 61-80, 80+ years), recent or long-standing diagnosis, single or multiple conditions, self-reported health status (good, mixed or bad on indicators of physical and mental wellbeing) and number of medicines (no, 1-5 or more than 5 medicines per day).

The age and gender criteria were applied to get a wide representation from different stages of life. The other categories were informed by the literature review (see chapter 2), notably the influence on expectations of medicines' effects from different experiences of living with ill health and how such expectations might change over time. By seeking representation of different numbers and duration of health conditions, I aimed to speak to people that had experienced from little to considerable ill health and contact with health care. Self-reported

physical and mental health status were used to achieve variation in terms of how people might associate CVD with being ill or healthy, and also to include patients that might both manage well and struggle with their daily life. The number of medicines used every day was used to allow for results to possibly be examined in relation to the quantitative literature on polypharmacy.

The number of included participants was not decided beforehand, but instead determined in relation to the analysis of data, which ran alongside data collection. When no new or relevant insights are added by additional interviews, the data material is regarded as saturated with information about the researched phenomenon and data collection ends.[94]

#### *4.4.5 Limitations of the recruitment methods and inclusion criteria*

Since the setting for this study is UK primary care, I recruited patients via GP practices. This limits the potential participants to people that have at least some contact with the NHS and that are likely to have heard some description of CVD risk being presented by their GP. The search criteria, which aimed to find one group of patients that had been diagnosed as ‘at 20% or greater risk for CVD within 10 years’ and prescribed one or more medicines to manage the risk, and one group that had experiences tangible heart-related ill health, were chosen to identify patients with a range of possible views on CVD risk. Other sets of search criteria, for example focusing on particular risk factors (such as type II diabetes, smoking, obesity or previous myocardial infarction) had also been possible to apply in order to reach people at risk for CVD.

### **4.5 Data collection**

Several methods of data collection are possible to learn about patients’ understanding of medicines, for example focus groups, participant observation, case studies and various forms of interviews.[173] They all have the potential to generate new knowledge about the research topic, but differ in the type of accounts that might be made available. Focus groups could encourage sharing of experiences and discussions between patients and thus reflect multiple angles, but at the cost of less depth of individual accounts and less opportunity for the researcher to follow up particular issues. Observations could offer insights into practical aspects of medicine usage, but that was not the scope of this particular study. Case studies and narrative interviews would be a way to explore in depth certain participants’ sense-making, but might produce findings that would be quite difficult to apply to a larger context. Considering

my aim to explore a combination of biomedical and social understandings of risk, medicines' role in managing risk and what might influence how patients make sense of it all, I chose semi-structured interviews as the method for data collection. This approach uses conversation between the researcher and the participant to gather knowledge from experiences, opinions and beliefs while allowing for many different types of descriptions to be shared and developed. The interview method was mainly informed by Kvale and Brinkmann's discussion of qualitative research interviewing.[172]

My approach was that each interview was an opportunity to create new knowledge in the interaction between a participant and myself in the role of researcher. To be able to fully engage in the conversation and focus on what participants were telling me, I recorded all interviews digitally. The recordings were then transcribed verbatim for analysis.

#### *4.5.1 Arranging interviews*

Patients who returned the questionnaire stating their interest in participating in the study were contacted via telephone. The sampling frame was used to prioritise which respondents to approach. If I could not reach a patient after repeated attempts (typically trying for two weeks after the arrival of their declaration of interest), they were removed from the list of possible participants. When calling the potential participants, I confirmed their interest in the study and explained what it would entail to participate. Interviews were arranged at the participant's convenience, either in their home or at the University.

#### *4.5.2 Consent*

All interview sessions started with a brief explanation of each point in the consent form (appendix A6), outlining how the recorded and transcribed data would be stored, protected and used. All participants consented to interviews being recorded digitally and data being used for research purposes. The form was signed by the research participant and me before the recording started.

#### *4.5.3 The interview schedule – preparing to gather information about my research topic*

The interviews were guided by an interview schedule which was adjusted during the course of the study to incorporate further exploration of emerging findings (the initial and final versions are shown in appendix A9). Since the recruitment of interview participants took longer than

expected, the two literature reviews described in chapters 2 and 3 came to run alongside the empirical data collection and therefore informed my interview questions.

The interview schedule consisted of open-ended questions and prompts for following up answers. The questions manage the overall course of the interview, including ‘ice-breakers’ and concluding phrases, and the prompts are sub-questions for the researcher to use so that as many aspects as possible are covered.[172,173]

Questions and prompts are connected to the theoretical background of the study, in terms of concepts to test and what type of information the researcher is looking for. My interview questions were formulated from the research question following the process described by Wengraf, where concepts from theory and previous research that informs the study are ‘operationalised’ via theoretical research questions to empirical indicators that are useful as interview questions.[177] For example, the assumptions about societal influences on patients’ expectations of benefit from medicines that make up the characterisation of pharmaceuticalisation [56] (see chapter 1, section 1.3.3) informed theoretical questions which in turn shaped the development of my study protocol and the interview schedule. In conversation with participants, these concepts were addressed in terms of where the participant might look for information about medicines and how they regarded information from different sources.

The questions were designed to contribute both thematically (to support the knowledge production) and dynamically (to support the interaction between participant and researcher) to the interview.[172] Thematic contribution came from direct questions about the participant’s experiences with CVD and medicine-taking, while dynamic contribution was sought by adapting the conversation to explore health-related issues that participants themselves brought up. Open-ended questions were used to elicit responses that showed participants’ reasoning around the topic, and also give a hint about how they had understood the question. In addition to the prepared questions and prompts outlined in the interview schedules, direct and indirect questions were used during the interviews to follow up, explore and clarify topics that the participants mentioned. To simplify my own use of the interview schedule, and thereby keep as much focus as possible on research participants, I constructed a graphical representation of the questions and prompts (see figure 4.a).

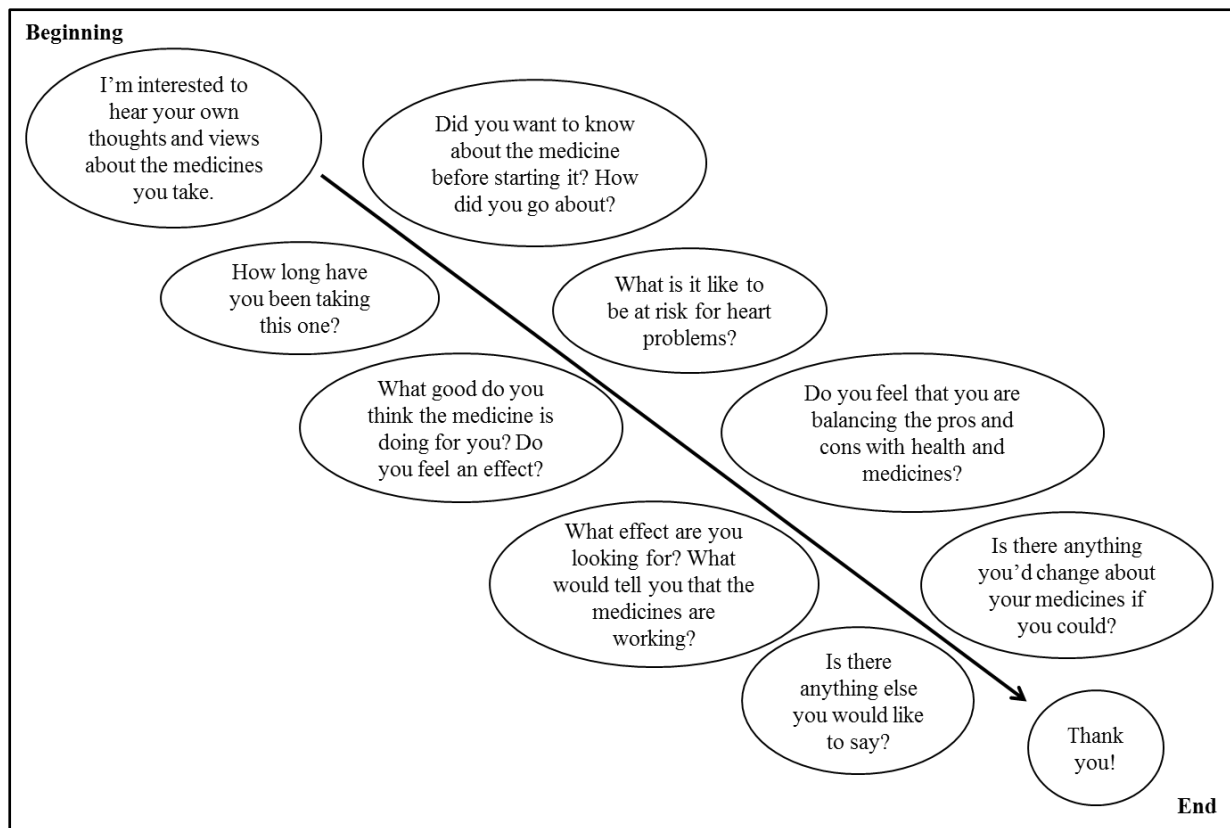


Figure 4.a The graphic version of the interview schedule. A full version is available in appendix A9.

Early questions focused on opening the interview and emphasising that the study was about participants' own views and experiences of using medicines. From these questions I aimed to get an initial picture of whether medicines represented something significant or un-interesting, whether medicines seemed to take up a lot or a little time and effort and whether they fit into or disturbed the participant's daily life. Circumstances around the start of the treatment were elicited to guide further questions about experiences and views of for example health screening or acute illness.

The following questions and prompts focused on any medicines mentioned as being used for cardiovascular conditions; "for high blood pressure", "for the heart" or "for the cholesterol". These questions sought to elicit what information about the condition and the medicines the participant had been given before treatment started, how the participant found it using the medicines, and whether there had been any evaluation of the effects of the treatment. One question addressed patients' need for information and usage of information sources, with prompts to test where information was sought (internet, friends and family, professionals, written information such as patient information leaflets or books) and how they valued

information from different channels. Participants' balancing of health risks and possible benefits and harms from medicines was addressed in questions about whether the participant found it worth the effort to take medicines every day, and if there was anything they would want to change about their medicines. Interviews were concluded with a question that let the participant address any topic that they might think had been omitted: "Is there anything more you would like to say?"

As expected, the interview schedule was changed during the course of the fieldwork. Participants told me things that I had not previously thought to put in connection with each other, and surprising replies served as new prompts in later interviews. Statements from early interviews could be used to challenge or question participants at a later stage of the study, in the form of "some people say it's like this, what do you think about that?" Changes were also brought about by my growing experience in the interview situation and in the role as a researcher. Every completed interview introduced adaptation and development of the interview questions in the following ones, since statements and replies from participants challenged my previous views of how things might be connected.

#### *4.5.4 Interview structure – finding out about participants' experiences*

A semi-structured interview is not a test of the participant's formalised knowledge. Neither does the researcher expect the participant to deliver statements that directly convey comprehensive 'solutions' to the concepts that are discussed. Instead, the interview is an occasion where new knowledge is constructed in the interaction between the researcher's pre-understanding of the topic and the participant's shared experiences, opinions and thoughts.[172]

The seemingly simple opening question "Can I start by asking you what medicines you are using at the moment?" elicited some short, factual answers focusing on medicines' names and some long, narrative responses that included both formal diagnoses and personal reasons for using medicines. Based on these initial descriptions, I continued with questions from the interview schedule adapted to the situation. In accordance with the analogy of mining and travelling (see section 4.3), most of the interviews followed the 'travelling' trajectory since my questioning was closely adapted to how participants answered my questions or brought in topics to the conversation. However, 'mining' questions were used to explore concepts that participants seemed to have given considerable thought or when they surprised me with an answer that I needed to try and make sense of in the moment.

By adapting the questions towards medicines or a diagnosis mentioned by the participant, I sought to elicit examples of how the CVD risk condition and possible management of it had manifested itself or been presented to them – how they had made sense of the situation and which decisions they had made. To be able to compare patients' views with a biomedical way of showing clinical effectiveness, I was also interested to specifically hear patients' thoughts about the evaluation of prescribed medicines – whether they thought or felt that the tablets did something good. Participants' balancing of health risks with possible benefits and harms from medicines was addressed for the same reason.

The findings in the literature review (see chapter 2, sections 2.4.1-2.4.4) were tested during the interviews, to develop the understanding of patients' expectations on medicines that are prescribed for the purpose of risk management. For example, one theme showed how patients might anticipate specific effects from medicines. Another theme was the development and adjustment of expectations over time. In the interviews, I explored these concepts in relation to CVD risk management by asking participants what they thought the tablets were doing for them and whether their opinions had changed over time and with experience of using medicines.

To conclude the interview, and to signal to patients that the meeting was coming towards an end I used the phrase "Now I think I have asked you about the things I had thought of before, is there anything more you want to add or discuss?" Thus, participants were invited to show what they thought was important in what we had discussed or if some valuable aspect had been omitted. Finally, I thanked participants for their time and contribution to the study.

After each interview I noted down my impressions from the encounter together with structural aspects of the conversation, as support for the data analysis.[94,173] Examples of these types of notes were things that might have shaped my questioning during particular interviews; emerging thoughts about what had motivated participants to join the study and how the location for the interview influenced the interaction. A pseudonym was assigned to each interview participant by using a method that was suggested in qualitative research online forums: I chose a name with the same initial letter as the participant's name that was popular in the decade when they were born. An advantage of this technique is that some consistency is kept between 'voices' in the data and the generation they stem from.



## 4.6 Data analysis

In my analysis of participants' accounts, I took the approach described by Kvale and Brinkmann as 'interview analysis focusing on the meaning'. [172] It entails finding information that is meaningful in relation to the research question among the many stories told during interviews, connecting that meaning to the research problem and then constructing a new story that can be told to show and share the new knowledge that was created between researcher and participants. In order to construct that story, I needed to condense the interview transcripts into an interpretive framework that displayed the new knowledge created in my study.

As my objective was to develop new theoretical understanding from the empirical data, I took an inductive stance throughout the process. The inductive approach means that the analysis is driven by what is found in the data, with questions and hypotheses evolving and being tested throughout the process. This differs from a deductive analysis, which looks at the data using pre-formulated questions or theory and seeks to test or confirm certain concepts. [96,100,172]

An inductive approach, however, does not isolate the analysis from the researcher's previous knowledge derived from theoretical or empirical examinations of related topics. Obvious influences on my attention and understanding were the literature reviews presented in chapter 2 and 3, which had highlighted aspects of individualism, responsibility and expectations of specific effects from medicines as issues to explore further. The conceptual framing of the study also contributed ideas that informed my analysis.

For the organisation, interpretation and synthesis of participants' many contributions of knowledge about the research topic into the 'researchers' story', I applied thematic analysis. [137] Given my choice of a critical realist perspective, [91] this flexible analytic method can accommodate for various types of understanding and meaning attached to CVD risk and medicines among research participants and in relation to the frameworks that informed my analysis.

The specific steps in my thematic analysis of data [100,137] were a combination of methods used in many qualitative research techniques; open coding and categorisation of data extracts based on constant comparison of meaning [178] and condensation of data by means of using a coding frame. [94] An overview of the process is shown in figure 4.b, and each step is described in the following sections.

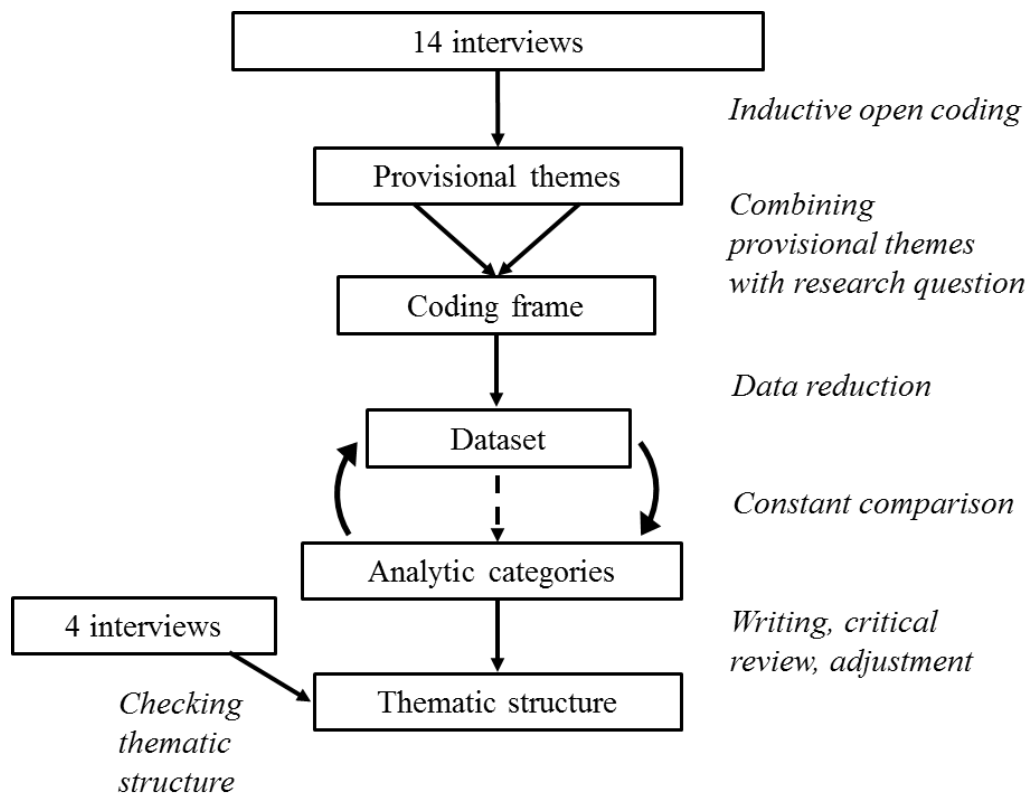


Figure 4.b Overview over the analysis steps. Text in italics shows the use of different methods throughout the process.

#### 4.6.1 Defining data

Following on from the ontological and epistemological views in this study, I regarded many different types of information as possible contributions to the descriptions of CVD risk and risk management. Data in the study were not only ‘results’ indicating for example presence or absence of certain features in participants’ accounts.[96] All parts of participants’ accounts were seen as data, including their answers to my questions and the way that they shared examples and stories. For example, biomedical and social accounts of reality were allowed to exist side by side or complement each other as I constructed the story about patients’ understanding of CVD risk management. Practically, it meant that I did not seek in any way to dispute or deny the presence of a real CVD risk in patients (for example individuals’ likelihood of suffering a cardiovascular event being higher than average), but I simultaneously looked for other descriptions of risk and medicines’ effects. Moreover, my field notes – recorded impressions from each interview encounter – and notes collected throughout the analysis process added to the data.[178] The field notes provided contextual information to each of the

accounts by reminding me of whether participants seemed for example interested, nervous or relaxed when talking about medicines and their health or whether things happened during the conversations that might have influenced what we talked about. Notes recorded throughout the analysis process helped me move from details towards more general descriptions by becoming a bank of emerging explanations to be tested, developed or discarded as the analysis proceeded.

#### *4.6.2 Inductive open coding to identify early themes*

My structured examination of the interviews started in parallel with the fieldwork. All interviews were first considered in their entirety – by listening to recordings while reading the verbatim transcripts – so that I would get familiar with the data and refresh my memory of each particular conversation.[137] Early reading of the transcripts was also an opportunity for me to reflect on how the questions and prompts shaped the conversation. Critical reviewing allowed for adjustment of the interview schedule according to emerging findings that challenged any *a priori* concepts from the planning of the study. An example is how I refined the interview schedule as I gained experience of how participants described their CVD risk conditions, see appendix A9.

After getting an overview over the transcripts, the first step in structuring my whole data material into a dataset in which I could search for themes was to do an inductive open coding.[94,173] This is a way of identifying words, sentences or longer pieces of text that relate in some way to the researched phenomenon. Assembling examples like this transfers the foundation for analysis from the many individual accounts to one rich and diverse collection of descriptions of the phenomenon under study.[100]

In my study, this meant reading the transcripts line-by-line while identifying and collating examples that showed or explained something about how participants made sense of CVD risk and risk management. My attention was directed towards information that related in some way to the conceptual framework and my research question: knowledge, personal experiences or stories about what other people do, how health care professionals act and how the pharmaceutical industry works. The process entailed listening back to the interviews and reading the transcripts closely and critically; marking, examining and comparing information. Field notes from the interviews were also reviewed; characteristics of each encounter and my notes of impressions from the interviews added to the richness of participants' descriptions and helped indicate context and meaning. Markings and comments were labelled with a word or short phrase, and I used both purely descriptive and interpretive labels.

In order to capture as many aspects as possible of participants' experiences of CVD risk and risk management I included many different types of descriptions. Examples include practical matters, personal experiences and hypothetical scenarios, examples from patients' own lives or those of others, general thoughts about medicines and health care and specific statements about certain situations. At this stage, I recorded labelled data extracts along with notes of my reflections during the process (questions, possible explanations, apparent connections, contradictions) in the form of mind maps. This deliberately wide method identified many different possible entry points for a more focused, interpretive analysis. It also helped me to find relations in the data – both between and within cases – as well as gaps that needed to be addressed in coming interviews.

For the purpose of producing anything but a superficial, descriptive account I needed to narrow the analysis and focus on a few themes that were directly relevant to my research question.[137] This would also allow me to move beyond particular examples shared by participants towards an interpretive, theoretical account. To concentrate my analysis on concepts central to the study, I reviewed the mind maps and picked out two central, provisional themes among the many descriptive labels. They both had great relevance for the research topic and the conceptual framework, and also were present in some form across all interviews: 'blood pressure' and 'medicines' effects'.

#### *4.6.3 Constructing a coding frame*

In order to do a structured and full exploration of the provisional themes I created a coding frame around them.[94,100] The construction of the coding frame was informed by Miles and Huberman's [94] suggestion about coding for general domains, such as activities, relationships, strategies and perspectives, within the data. Moreover, I used what Strauss and Corbin [178] refer to as sensitising questions (identifying actors, actions, meaning) and theoretical questions (searching for conceptual relations and how events and actions develop over time).

To keep my analysis focused on the research topic, I used my research question and the provisional themes from the open coding instead of the general domains when I constructed the coding frame. Three central concepts from the research question; 'influences', 'understanding' and 'risk management' were thus combined with 'blood pressure' and 'medicines' effects'. By formulating questions around these words, the coding frame would help me examine the data in a focused way while still capturing many different aspects and possible meanings of phenomena. Examples of the questions are 'What is high blood pressure?'

(combining ‘understanding’ and ‘blood pressure’) and ‘How do you learn about medicines’ effects?’ (combining ‘influences’ and ‘medicines’ effects’). The full coding frame is shown in table 4.3.

Table 4.3 The coding frame for condensation of the whole data material into a dataset for further analysis.

<b>Provisional theme</b>	<b>Concept from research question</b>	<b>Coding frame component</b>
Blood pressure	Influences	Which are the involved stakeholders; who does what? Which actions – prompted or discussed – are related to discovering or having high blood pressure
	Understanding	Descriptions – what is (high) blood pressure? How is it made sense of?
	Risk management	What does the risk mean – (how) is it enacted and related to ill health? (How) can the risk be managed?
Effect from risk management medicines	Influences	Looking for information before starting treatment? Which information sources are used? What do different information sources say?
	Understanding	What does it mean to use medicines for risk management?
	Risk management	How do medicines work? What do the medicines do for you and other people?

#### 4.6.4 Coding

At this stage, I started using the qualitative data management software NVivo 10 [179] to organise data in the coding process. Transcribed interviews were imported one by one in full-text format and coded line by line in the search for words, sentences or longer bits of text that related to any of the questions in the coding frame. Extracts coded as related to a specific question were collected using the ‘Node’ function, which allows for comparison across sources, e.g. transcripts. During the coding, I strived to minimise interpretation of the extracts in order to produce a rich and detailed dataset that retained the broad range of associations around each aspect of the coding frame. A generous approach was used, including whole sentences or parts of paragraphs rather than singular words so as to not lose any richness in descriptions.

This dataset produced by the applying the coding frame was the starting point for further analysis: interpretation of how and why certain things influence patients' understanding of CVD risk and benefits from risk management medicines.

#### *4.6.5 Categorising and interpreting*

To start constructing my theoretical account from the collection of examples and descriptions related to the components of the coding frame, I needed to order the data according to my emerging interpretation of what it showed. This was done by way of reviewing the dataset and combining the coded extracts into categories on the basis of what they described and how they were related to each other.

The categorisation started within data that had been collected under each 'Node' in NVivo10 [179], that is, among extracts that referred in some way to one of the questions of the coding frame. Parallel to examining the dataset, I reviewed my field notes from each interview in order to assist my understanding and interpretation of each particular extract. By also returning to the interviews in their entirety, I reminded myself of the context of coded extracts. Things such as the framing of statements in a narrative about a personal experience or an account of what 'people in general' think, or whether the mentioning happened in passing or was part of a reiterated statement provided additional layers of meaning to the data extracts and was helpful when placing it in categories. I did this stage of analysis without the support of NVivo 10 [179], for fear of the software introducing constraints on the creative and intuitive process of finding and testing associations across the dataset.

Throughout the allocation of data extracts to categories, the categories were continuously reviewed and adjusted so that they accurately reflected all aspects of data included in them, but without overlapping with other categories. This technique is often referred to as constant comparison.[96,137] Each addition of a data extract to a category brought the analysis forward as it got incorporated into the construction of knowledge about CVD risk management and using medicines.

Since the participants were sampled using the maximum variation technique, I paid particular attention to relations between extracted data; whether statements and explanations confirmed or contradicted each other, whether some findings seemed typical and other different, and how this might be related to certain characteristics.[94] For instance, apparent contradictions between participants' viewpoints encouraged me to look for possible explanatory factors within

the different accounts. This took the analysis beyond comparison of separate accounts and on to a more abstract level – thereby starting to construct a theoretical description and forming the ‘researchers’ story’.[172]

It should be pointed out here that the data extracts were not handled as calculated units contributing towards an overall ‘tally’ of views or descriptions, but as entire explanations in themselves. A different view of data would handle the deviant case as an outlier or see an 1:n ratio of opinions. However, all explanations did not essentially get represented in the final account – my aim to construct a coherent theoretical description made the process of construction subjective rather than objective. As my attention was directed towards structure and relations that were present in the data (instead of seeking to test a pre-formulated theory), this subjectivity becomes a way to represent the participants’ views rather than a specific theoretical description in the emerging analysis.

The categories derived from each of the dimensions of the coding frame were then brought together for overall comparison, combination and ordering into clusters. Also here, patterns of similarity or contradiction and gradients of phenomena were used as clues to identify relations and explanations. Critical review of data within and between categories continued, since every new addition was examined in relation to the overall, emerging story.[137] Here, I also actively used theoretical ideas from the conceptual framework and findings from the two literature studies to interrogate the emerging findings.

#### *4.6.6 Developing and testing themes*

As a thematic structure started to form within the dataset, I began testing it by means of writing the theoretical account; the ‘researcher’s story’. The writing process helped me test emerging associations and explanations [137] by showing whether they could be re-told in a meaningful way. It also identified areas of imprecise thinking and gradual differences in the application of the coding frame. Sharing the writing with Prof Walley and Dr Reeve served as an additional method of testing whether interpretive ideas held together as stories, by revealing ‘dead ends’, inconsistencies and gaps that needed further exploration. Interpretive findings in the form of hypothetical questions and suggestions about possible explanations continued to be recorded as field notes and discussed within the research team.

Throughout the iterations of writing and critical review, which focused on the interpretive structure for my data, I also revisited the interviews in their entirety to check that the emerging

themes still reflected them in a truthful way.[137] Although my aim was to do a thorough analysis of a few central aspects rather than give a full description of the whole dataset, I wanted to ensure that the interpretation had not moved too far beyond particular accounts or introduced any contradictions. The critical reviewing was accompanied by continuous changes to the category names and their structure.

After several rounds of critical review of the emerging findings and subsequent re-structuring of data, the categories formed a robust thematic framework describing patients' views of CVD risk management. At this stage, I tested the framework by doing a line-by-line coding of the four last interviews. The remaining data did not challenge the thematic structure, for example by introducing a need for changes to the categories or completely new ideas. Thus, I considered the analysis finished.

The final description of patients' understanding of CVD risk management is presented as a framework of two major themes based on a structure of sub-themes and categories; see chapters 5 and 6. Interpretations are presented as a written account of what it means to be at risk for CVD and how medicines' effects are assessed, supported by quotes showing how patients expressed different aspects of risk management.

#### **4.7 Assessment of validity**

Having shown how I condensed my 18 research participants' individual stories and examples into one theoretical account of patients' conceptualisation of medicines in CVD risk management, I turn to the question of the validity of my findings.

Since this study aimed to explore patients' understanding of health and medicines beyond what is included in a positivist paradigm, the assessment of validity is not concerned with proving representativeness or generalisability of the findings in a numerical way. Instead, validity will be evaluated against aspects of how research methods, the collected data and my interpretation hang together and whether the findings are useful knowledge for answering my research question. An important aspect of validity is also that it is not a set of 'checks' at the end of a study, but something that needs to be built into and reflected on throughout the research process.[172]

In studies with sub-samples or many researchers, formalised comparison of coding and triangulation of datasets can provide ways to test the robustness of codes and emerging



analysis.[94,100] As this study was done by only me, I relied on discussions with Prof Walley and Dr Reeve for external evaluation of explanations and the developing story.

For reflections on validity and usefulness of the findings in the study, I used Lincoln and Guba's [96] criteria for trustworthiness. The criteria entail a questioning of 'truth value', 'applicability', 'consistency' and 'neutrality'. These terms correspond to testing of internal and external validity, reliability and objectivity within a positivist view of knowledge by questioning the contingency of findings on characteristics in the sampled participants and the design of the study, and whether the findings hold true across populations and contexts. To add a more specific examination of the process of producing new knowledge, I included aspects of Kvale and Brinkmann's [172] criteria for validity in interview studies.

#### *4.7.1 Criteria for the assessment of validity*

The first aspects that I will consider are the conceptual framing and planning of the study. This includes a review of its design and whether sampling and recruitment were done in order to produce useful and valuable knowledge.[172]

The next aspect considers the truth value and neutrality of my findings.[96] It brings together reflections on the authenticity and credibility of the things I report, and includes questioning of how my choices of research methods influenced the production of knowledge. Truth value describes the extent to which the created and presented knowledge represents things that would be considered true by the participants. Neutrality refers to whether the research has led to findings that are determined by participants' views on the research topic rather than shaped by the researcher's biases, motives or perspectives. Moreover, this part of the evaluation looks at how answers and examples shared during interviews, including the transformation of talk into text, represents participants' contributions. It also addresses whether my analytical questioning of the data has produced a truthful account of what participants meant and thought.[172]

Finally, I will assess how my findings relate to the surrounding world by reviewing the applicability and consistency [96] of my research. This means to question whether the findings would be useful also in other circumstances – for example in relation to other types of prescribing or use of health services – and to what degree they would be similar if the study was repeated in a comparable population and context. This part of the criteria also considers how to critically assess validity in the study, including inviting readers to do their own validation.[172]

The set of criteria that I applied when reviewing my study is shown in table 4.4. An account of my application of the criteria in critical evaluation of my study is given in chapter 8.

Table 4.4 Criteria for the assessment of trustworthiness and validity [96,172]

Criteria	How I will demonstrate it
Conceptual framing and planning	By clearly stating the theoretical background for the study and how it is connected to sources of information, research questions, interview questions, recruitment and sampling for the study.
Truth value and neutrality	By giving a transparent and detailed account of how I collected, handled and analysed data, including reflections of experiences from interviewing.  By critically reviewing (alone and together with others) the structure and content of the emerging interpretation.
Consistency and applicability	By producing an account that is grounded in existing theory and developed with awareness of influences from structural factors (participants' characteristics, my positionality) and thereby allows for comparison with other research areas.  By presenting my data analysis and findings in a way that invites critical review from readers.

## 4.8 Summary

This interview study sought to create knowledge that would help answering the research question “How do patients conceptualise CVD risk management medicines?” It was designed with reference to a conceptual framework which outlines the major relations and actors that I anticipated would be influential. The framework highlights patients’ knowledge in medicine usage and the reliance in current health care policy on data produced with a focus on a biomedical understanding of pharmaceuticals.

A critical realist stance accommodated for the creation of new knowledge in a way that acknowledges that there can be more than one meaning to ‘CVD risk management’. The biomedical definition of it might not encompass all representations that have bearing on the

use of medicines prescribed in conjunction with it. In order to explore patients' understanding of the matter, I applied methods of data collection and analysis that would allow for research participants' sense-making, experiences and ideas about meaning to be included alongside formalised knowledge.

Data – in the form of patients' stories, views and thoughts about using medicines – were collected in semi-structured interviews and as field notes and reflections alongside the analysis process. Prior to thematic analysis, I condensed the data material by means of using a coding frame constructed around the research question and central concepts in the data. A constant comparative technique was used when categorising data extracts. The combination of data across accounts highlighted themes that explained or described phenomena beyond the individual stories, and those themes formed my theoretical description of patients' view of CVD risk management. The trustworthiness of my research and its findings has been supported by critical review and discussion throughout the planning, data collection and analysis.

Having described how data were collected and analysed, I will now present the new knowledge that was created in the study.

## Chapter 5

### Findings I: Being at risk

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#### **5.1 Chapter overview: Findings**

In this chapter and the next, I present and discuss the results and findings in my interview study. Each of these chapters contains a descriptive account of one of the major themes, which is followed by a discussion section where the findings are linked to theory. Together, the chapters show the thematic structure for patients' understanding of medicines in CVD risk management that was the outcome of my analysis.

An overview of the results of the recruitment and participants' characteristics is also given, to provide some context to the quotes that are part of my account of the findings (for the full record of characteristics, see appendix A11). Then I display the first theme, which is about being at risk for CVD. It shows how the risk assessment and identification of risk factors, which are core tasks in CVD prevention in primary care, are perceived by patients.

#### **5.2 Recruited participants**

As described in chapter 4, section 4.4, I applied a purposive sampling strategy to recruit participants for the interview study. Of the 28 people that responded to the invitation, I included 18. This was after three people had not been possible to reach for arranging an interview, one person had declined upon being contacted by telephone, one person had concluded that we would not be able to meet during the course of the study due to him recently having had surgery and five people corresponding to parts of the sampling frame (see appendix A8) that were already filled. An overview of the 18 participants that were interviewed is shown in table 5.1. The single largest category of participants that replied to the invitation to participate in the interview study were men between 61 and 80 years of age, who were at low risk for CVD, used between 1 and 5 medicines every day and managed to do most daily tasks without assistance. In addition to this group of participants, I also recruited men and women from the age span 41-60 to +81 years at low and high CVD risk. All people that replied were taking medicines to manage CVD risk; using between 1 and 5 or more than 5 medicines daily.

In relation to the initially planned purposive sample of participants of different age with an expected variety of experiences of CVD risk, illness and medicine-taking, I did not manage to recruit anyone in the age-span 18-40 years, anyone who did not take any medicines and any female participants at high risk of CVD or over the age of 80.

Table 5.1 Overview of the participants

<b>Name</b>	<b>Risk level</b>	<b>Age</b>	<b>Health-related characteristics</b>
Holly	Low	41-60	Lifelong experience of somatic conditions and use of pharmaceuticals, describes herself as healthy
Richard	Low	61-80	No experience of symptomatic illness, declining memory
Albert	Low	61-80	No experience of symptomatic illness
Anthony	High	61-80	Previous experience of cardiovascular condition; has had a heart attack and is under current investigation for heart symptoms
Nathan	Low	41-60	No experience of symptomatic illness, has had problems with side effects from medicines
Gerald	High	80+	Previous experience of cardiovascular and other conditions; has a pacemaker
Rose	Low	61-80	No experience of symptomatic illness
Alfred	Low	61-80	No experience of symptomatic illness, has had problems with side effects from medicines
Norman	High	61-80	Previous experience of cardiovascular condition; has a pacemaker
Paul	Low	61-80	No experience of symptomatic illness, has had problems with side effects, from medicines
Joyce	Low	61-80	Previous experiences of somatic conditions
Judy	Low	61-80	Previous experiences of somatic conditions
Michelle	Low	41-60	Lifelong experience of somatic conditions and use of pharmaceuticals, experience of dependency, depression
Fred	High	61-80	Previous experience of cardiovascular condition; has had a bypass operation, has a pacemaker
James	Low	61-80	Previous experiences of somatic conditions
Samuel	Low	61-80	No experience of symptomatic illness; depression
Stephen	Low	61-80	Previous experiences of somatic conditions; anxiety
Tobias	High	80+	Previous experience of cardiovascular condition; has had several heart attacks

### 5.3 Introduction to the thematic structure

Two main themes – ‘being at risk’ and ‘seeking stability’ – form the structure for a framework describing patients’ conceptualisation of CVD risk management. They are built up by subthemes that focus on a chain of aspects of diagnosis and treatment of high blood pressure: initial and long-term interpretations of being at risk for CVD, the decisions made regarding interventions, and how treatment strategies are evaluated. Table 5.2 outlines the structure of themes and subthemes and shows how the descriptive categories come together to form a picture of CVD risk management from a patient perspective.

It should be noted that the appearance of a chronological order between the categories is a product of my analysis, and represents neither a chain of reasoning nor a narrative structure that was uniformly present in patients’ own stories. The category structure is a matter of data presentation, which has the advantage that it facilitates comparison with the clinical approach of identifying, diagnosing, intervening and evaluating outcomes.

Table 5.2. Overview of themes, subthemes and categories.

Themes	Subthemes	Categories
<b>Being at risk</b>	Initial reactions	negative feelings // indifference
	Contextualising	causes and explanations // consequences
	Taking action	medical information // personal representations
	Cohort strategies	individuals // systems
<b>Seeking stability</b>	Individual assessment of effects	experiencing // seeing // interpreting // balancing
	Thoughts about future outcomes	for myself // in general

Data are presented as descriptions of the categories one by one, supplemented with quotes from participants to show examples of how they described things. A few quotes from participants have been slightly amended for readability, but with care taken to preserve the individual voices as they together with the words mediate the meaning. In some places, my question is included to show what we were talking about, and this is indicated in italics.

## 5.4 Being at risk

This theme shows how patients conceptualise being diagnosed with a condition that means they are at risk for CVD (see table 5.3). Stories and information shared by participants about having high blood pressure show their reactions to and reasoning around the diagnosis and the decisions and actions that it gives rise to. This theme consists of four sub-themes: ‘initial reactions’, ‘contextualising’, ‘taking action’ and ‘cohort strategies’. The order of the sub-themes progress from being diagnosed with high blood pressure, making sense of it by placing it in a context of causes and effects, which sources of knowledge are used and how, and what the reflections and conclusions about plausible actions are.

Table 5.3 The first theme with subthemes and descriptive categories.

<b>Being at risk</b>	<b>Subthemes</b>	<b>Categories</b>
	Initial reactions	Negative feelings
		Indifference
	Contextualising	Causes of and explanations for risk (before – what leads to CVD risk?)
		Consequences of risk (after – what will CVD risk lead to?)
	Taking action	Medical advice and information
		Personal representations of the need for intervention
	Cohort strategies	Individuals and populations
		System critique

## 5.5 Initial reactions to the identification of a risk factor

This theme outlines how participants first made sense of being diagnosed with high blood pressure or cholesterol. Some got the diagnosis at a routine visit to the GP, others while being treated for other illnesses including CVD-related problems.



### *5.5.1 Negative feelings*

Many participants in the low risk group expressed some astonishment related to finding out that their blood pressure was high; they had not noticed any symptoms. For some, it was difficult to come to terms with the diagnosis of a risk factor or a heart problem because it was interpreted as something quite serious that had been uncovered. This was the case for Holly, who saw CVD risk as something different from her other chronic health problems that she was used to having and which did not stop her from enjoying her life fully.

“... because I didn't mind having... I didn't mind having things that weren't going to make me ill, like my psoriasis and my arthritis and stuff they are not going to make me ill, but my high blood pressure is something that could affect my life from a medical point of view. And that bothered me.”  
(Holly)

An element of surprise is mentioned by some participants, for example by Joyce, who reacted to being diagnosed with something when she had not noticed any problems herself.

“So really it was quite a shock that I had this because to me I didn't feel any different which you don't, you don't know you have got it do you?” (Joyce)

A description of the high blood pressure diagnosis as an unpleasant surprise was also shared by Rose. For her, as well as for Joyce, the diagnosis did not fit in with a previous views of themselves as healthy, not needing doctors and going through stages of life without using medicines. It is upsetting to learn from doctors' tests and statistics that this has changed.

“At first I was a bit cross because I have never had blood pressure, ever, ever, not through pregnancy, not through anything.” (Rose)

“It was a little bit of a shock to me because I had always been very healthy and never needed anything other than maybe a pain killer.” (Joyce)

### *5.5.2 Indifference*

Some participants, however, said they did not react very strongly to the diagnosis. They had learned about the blood pressure at a routine examination and were not particularly frightened by it. There was no apparent difference between participants conveying indifference towards

the CVD risk diagnosis and those being upset by the news; people in both groups were equally interested in keeping active and maintaining good health and quality of life. However, to some participants the identification of a risk factor did not represent something threatening.

“it was simply, something that happened which didn't surprise me knowing how other people my sort of cohort group... I mean it is not something you would normally talk about but you know, no, it was just very undramatic and very routine to me.” (Albert)

Another example of the un-scariness of the diagnosis was given by Richard, who has always looked after his health and feels he is still able to keep up with both social and physical activities. He told me how little the high blood pressure impacts on the way he lives his life, for example in contrast to other conditions that are more tangible:

“if it would have been something that was life threatening, even limiting me in sort of my activities then it would have had a much greater impact on me”  
(Richard)

Participants in the high risk group, who were using medicines after having had a cardiovascular event, referred to dramatic experiences surrounding the event when I asked how it was to find out about the heart problems. Norman described his first angina attack and Fred gave a vivid account of how he perceived the pacemaker operation.

### *5.5.3 Concluding the subtheme*

The information shared by a GP that there is a risk factor for CVD present appears to have the potential to be a significant event for patients. One group of participants describe a reaction that mirrors the approach in medical CVD risk management strategies – that it is beneficial and not particularly dramatic to identify the risk factor at an early stage. Other participants' strong reactions add dimensions to the strategy of screening for CVD risk for the purpose of prevention: it can be distressing to learn that your blood pressure is high enough to render a medical diagnosis, since it indicates something has changed that might influence your future life. There was no clear evidence of factors that could explain the different types of reaction; people of both genders, with and without previous experience of illness were present in both categories.

In contrast to the examples participants gave about finding out about their high blood pressure, there was a lack of similarly straightforward descriptions of reactions to a diagnosis of high cholesterol. This suggests a difference in how those two risk factors are perceived by patients, with high blood pressure being more accepted while cholesterol is somewhat contested.

## **5.6 Contextualisation**

Participants' descriptions of causes and consequences linked to the diagnosed risk – in terms of high blood pressure or cholesterol – are a source for understanding more about how they perceive CVD risk. This sub-theme shows how the diagnosis is made sense of and how it is fitted in with thoughts about health and life in general.

### *5.6.1 Causes and explanations*

Participants took different examples when telling me what might have caused their blood pressure or cholesterol to be high. These statements were not given as replies to direct questions about reasons for increased CVD risk, but often shared when I asked about the circumstances around when their medicines were introduced and whether they felt or thought the medicines were having beneficial effects.

All participants gave examples showing that they had some type of knowledge about what had caused their blood pressure to become high. A few of the mentioned factors were things that are possible for individuals to influence: body weight, diet and one's level of physical activity. Genetic makeup and family history were also named as explanations for high blood pressure, as was stress and other illnesses. Some participants had contemplated how different aspects of their lives and lifestyles contributed to their own condition. Norman was testing the idea of replacing the medicines with exercise, whereas Michelle, who was trying to cope with the effects of a long-term morphine treatment for a pain condition while also looking after her young children, saw her blood pressure as possibly related to all the daily struggles.

“But if I stopped taking pills and did a lot of exercise, would the [angina] pain go away or not, or would the blood pressure reduce itself, if I lost a bit of weight as well?” (Norman)

“I don’t know if the blood pressure would come down if I lost the weight, if I got in a better place, if I got rid of all the other rubbish, you know, that might come down too.” (Michelle)

Tobias’ explanation also draws on links between life events and cardiovascular health, but excludes the reasoning about diet and exercise. He had lived through several major heart attacks, and described how all the heart problems had come as a result of one particular event.

“... if I suffer a loss, I just think about that moment, I’m shocked. Like, my father died, it was the biggest shock in my life. And that’s why I got the heart problems, since then.” (Tobias)

Age as a determining factor was described by most participants as changing the body and making medical attention and intervention necessary. Together with your genes and family history of CVD – other internal, bodily causes that cannot be influenced – getting older meant that you could get high blood pressure despite having been healthy earlier in life, having had a physical job or making efforts to stay fit by means of eating well and exercising. High blood pressure is thus described as being brought on by some specific aspect of an individual’s life and not merely associated with risk factors. Richard, who was in the low CVD risk group and no previous experience of ill health, put it like this:

“Throughout my life I have been as fit as a butcher's dog really. I have been very much involved in sport, football and athletics [...] I used to go out running a lot to sort of try and keep fit. And I have never really been one for going into the doctors and never been on tablets so this is sort of a late life thing. [...] Well I was obviously disappointed that it had finally caught up with me, that was more a psychological thing than a medical thing.”  
(Richard)

The link between ageing and higher blood pressure was discussed further by Samuel, who was also in the low risk group:

“So many diseases, or so many illnesses come by age, like when we are children we get certain diseases, in that age group. So I am subject to this kind of old age illnesses, which is why I have the blood pressure.” (Samuel)

In conjunction with the naming of age as a reason for their high blood pressure, some of the low risk participants pointed out that the condition is common among their peers or in the population in general. The same reasoning was used regarding elevated cholesterol. This is a diversion from the otherwise person-centred examples used in descriptions of possible causes for CVD risk. In contrast to telling me how “all the guys at work” (Nathan) or “everybody over the age of 50” (James) are on the same types of tablets, there are no groups that are identified as not being exposed to the risk.

The explanations about lifestyle factors as causes for CVD risk were presented to me as based in people’s own thinking rather than as having been enforced by health care professionals. On the contrary, doctors’ and nurses’ actions are described as not supporting the view of lifestyle as a major influence; they focus on test results, charts, computer screens and prescriptions instead of giving advice on healthy habits. Norman, who mentioned several times during the interview that he used to drink almost every evening, did not seem to discuss that habit with his GP practice:

*Is it something that your GP has talked about, have they sort of suggested you can either go the diet and exercise road or you can take medicines?*

“No. She said I should lose a bit of weight, that is the last thing she said to me. She doesn't tell me to exercise, she doesn't tell me to stop drinking, she doesn't tell me to do anything, she just looks at the charts and the blood charts and checks my blood every year, or at least the nurse does. If things are the same as last year I don't get to see the doctor but if they have changed slightly, I get to see the doctor. She just weighs me, checks for diabetes, checks the bloods, tells me that my liver is ok.” (Norman)

### *5.6.2 Consequences of risk*

Another aspect of placing the blood pressure into a context was related to a consideration of the consequences it might have for one’s health. Participants in the high risk group who had already experienced one or several episodes of CVD symptoms, like Norman, referred to those and were afraid that might happen again.

“High blood pressure, angina attack, lost the use of this arm for about an hour. Scary so I went to the doctors the next day, he gave me two aspirins and sent me straight to the hospital so then they stuck a wire in the vein and

watched it all on TV. They couldn't find anything wrong, except I had high blood pressure. [...] Well, when you lose the use of your arm for a couple of hours, you don't want that coming back.” (Norman)

Participants in the low risk group, like Nathan and James who had been diagnosed with high blood pressure and cholesterol at routine examinations, also illustrated their views of potential consequences of high blood pressure by giving examples of serious outcomes. Strokes that may cause permanent disability and fatal heart attacks were two particular ones mentioned. Here, descriptions of the process of CVD risk assessment and suggestion about interventions hint towards it being a straightforward prediction of what will happen in the future.

“... having put all these factors into the PC it comes out with a figure you have 20% chance of having a heart attack by the time you are 65, I think oh rubbish.” (Nathan)

“They give you your threescore and ten don't they; you've only got ten years if you don't do this, don't do that. So I'll be dead in ten years, that's what they're telling you.” (James)

Less specific but still severe suggestions were given too: the diseases that follow high blood pressure or cholesterol could have detrimental effects on your life, causing suffering and need for heart surgery. Many related their fear for various outcomes to having seen it happening to family members, for example Holly who had learned about her high blood pressure at a relatively young age. The use of events in the family when giving examples of what the high blood pressure might lead to, suggests that people base their conclusions on their own limited experience of tangible events rather than anonymous but more representative data. Paul, who was in the low CVD risk group and needs only one blood pressure medicine to keep within target, also sees a clear link between his current diagnosis and future outcomes.

“My mother died from a stroke, my aunty died from a stroke, high blood pressure obviously is fundamental to that happening, and I know I wouldn't be prepared to take that chance to be quite honest with you.” (Paul)

“...whereas uncontrolled high blood pressure will give me a stroke and bump me off possibly, or give me a stroke and leave me permanently

disabled, which is a massive effect on your life when you are in your 40s and get told you have got high blood pressure, it was a real biggie” (Holly)

In both high and low risk participants, there is a sense of directness in the descriptions of consequences of high blood pressure; people refer to their diagnosed risk as something that is likely to harm them. This observation is strengthened by the absence of other ways of reasoning. An attitude often referred to in other risk situations (for example in relation to condom use for prevention of sexually transmitted infections and sun protection to lower the risk for skin cancer) of the type ‘it will not happen to me’ is not expressed by anyone.

### *5.6.3 Concluding the subtheme*

The causes and explanations echo lifestyle behaviours that tend to be mentioned in conjunction with cardiovascular disease prevention or indeed health promotion in general: diet, alcohol consumption and tobacco smoking. Age, excess body weight, lack of physical activity and stressful life situations or other medical conditions bringing about high blood pressure all mirror the biomedical descriptions of causes. Also the examples given as illustrations for the consequences of having high blood pressure are the same as those used in publicly available communication of CVD risk – participants allude to fatalities and severely disabling conditions and describe how family members have suffered from such conditions.

The identification of a risk factor and subsequent suggestions about treatment to manage it becomes interpreted as the presence of a disease that requires intervention to avoid catastrophic consequences. Moreover, the specificity regarding perceived causes as well as consequences might set the expectations for an equally specific intervention to manage it. This quote from Joyce, who was in the low risk group, shows how simple the relation might be perceived to be:

“You know, possibility of you dying, or taking a tablet; not a lot to choose is there?” (Joyce)

## **5.7 Taking action**

As shown above, high blood pressure is seen by participants as an important discovery with potentially severe impact on their own lives. This subtheme shows what actions participants considered taking in response to being diagnosed. It looks for confirmation or challenging of the patient behaviour that is implicit in strategies for health promotion that build on treating a

large group of people at low risk: acceptance of the biomedical rationale and engagement with treatment despite little obvious individual benefit.

#### *5.7.1 Medical advice and information about risk management*

Being prescribed medicines for CVD prevention was an inclusion criterion in this study; all participants had thus had a doctor suggesting that some pharmaceutical intervention would be beneficial. This category describes how participants had perceived the recommendation to manage the risk by treating their blood pressure or cholesterol, and let it inform their decisions about what action to take. It also shows how other sources of medicines information such as websites and patient information leaflets in medication packages were used when making decisions.

Descriptions around what doctors had suggested in response to elevated blood pressure and cholesterol centred on prescribed medicines. Participants that had been diagnosed at routine examinations described it as a very straightforward process that translated directly into intervention.

“They just said this is your condition, this is what we are going to prescribe for you.” (Richard)

“I have been prescribed tablets for hypertension of which I take two types.” (Nathan)

For some participants, the acts of diagnosing and prescribing seem to carry the proof that intervention was indeed needed. This conclusion was shared by Joyce, who was very concerned about doing the right thing with regards to her health, as well as Samuel, who took a more critical stance to the doctor’s advice.

“I don’t believe that they are going to give you a tablet that, you know, you are not really going to need, they give it to you for a reason, if they are a good GP surely” (Joyce)

“And you know, I take them out of necessity, not pleasure, because it’s been prescribed to me by the doctors.” (Samuel)

Others, like Holly who had very high blood pressure after a flare-up and subsequent treatment in hospital of another condition, did not at first want to accept the diagnosis. Holly asked to be



given some time to let it settle while she was getting home to her own routines. However, further testing kept showing the pressure was high and her doctor insisted it needed to be treated. After a period of trying to “get her head around it” she acknowledged that the blood pressure was high and should be treated.

“... it was still high and I am like yes, I have still got my joint problems, and all the stress of the hospital didn't do me any good. And they were really understanding, they said you can have your blood pressure done again in a fortnight. And then they brought me back another fortnight after that and after about six weeks they were like, we really need to treat this, we can't keep giving you an opportunity, you have to and that was it really.” (Holly)

When treatments were started, the recommendation to use medicines for the blood pressure had come with the information that it was going to be a life-long treatment. Participants seemed content that their doctors had been open about that fact, and accepted it. Not much other detail was given around the actual initiation of treatment; it seemed that starting to take tablets was less dramatic than for example learning about the diagnosis. A few participants had revisited the need for medicines after a period of treatment, but had been told they could as well carry on taking them since the blood pressure was not going to get better by itself. This argument was also accepted.

Some of the participants simply used the “doctor knows best” argument to describe why they had chosen to take treatment as their doctor suggested. However, others explained it further, telling me how doctors’ advice needs to be followed because it is based on something. Testing and examinations that had been done were given as examples of what underpin recommendations, as well as GP’s education, qualifications and professional experience. Richard, whose high blood pressure is his first reason to go “to the doctor’s”, trusts their recommendations to be the best for him. So does Tobias, who after his major heart problems might speak from experience of being saved by medical expertise.

“I would go for it. For one thing, I would always take the advice, unless it just seems completely unsuited to me and my circumstances. Generally speaking, if a doctor looked at my medical condition, all the tests, all the readings and everything else whatever there is and he or she made a judgement that I need to go onto whatever then I would just take it. I would never question their decision.” (Richard)

“They are the medical doctors, they’re professionals. So naturally they know their field, what they’re talking about when they are telling me something. Then why should I argue with them, like why are you saying this? No, it’s their field, they’re expert in it, let them decide what to do with it.” (Tobias)

Apart from notions of medical advice being suited to oneself, an indication of the perceived superiority of the doctor and of medical knowledge is found in Rose’s description of how she and her doctor made a decision about stopping treatment with statins after she had been taking them for a couple of years. She puts it in the words of getting permission to come off the tablets after a new risk assessment procedure shows her risk is only marginally elevated:

“The doctor said well, you can [come off them] if you like, because she did this Q test and things have changed over the years.” (Rose)

Doctors keep representing expertise when it comes to medicines even after participants had been using the tablets for some time. The idea of patients building their own expertise about conditions and treatments over time (see chapter 2, section 2.4.2) was used as a question to challenge participants’ statements about the dominance of biomedical knowledge. I formulated it something like “Some people say well, the doctor knows about medicines and diseases but I know about my own body and how I feel when taking the medicines – what do you think of that?” Sometimes I was refuted with arguments of the type “my doctor knows a damn sight more than I do about it” (Albert) and sometimes participants offered descriptions of how to negotiate and combine the two types of knowledge. One such example is given by Judy, who has had breast cancer a few years ago and relates our conversation about risk and health to her experiences from that period.

“I listen to my body, and that’s when I was, it was advised by that GP that I needed to take these blood pressure tablets I just thought ok, yes if that is what my body is saying but also listen to it and, do what you feel is good for you, so...” (Judy)

Samuel’s explanation displays another way of combining one’s own formal knowledge with that of medical professionals, but also with the tacit understanding that comes with experiencing health, illness and medicines.

“All right, I believe in science and I have a verified education myself. So science to me is God, that’s what it is. So you cannot just dismiss it. Although you know exactly what’s good for you because you live inside your body, your body lives inside you, so you know what works and what doesn’t. But still, you leave that grey area where you say “well, this is science; I just have to accept it that way.” (Samuel)

However, the trustworthiness of doctors’ advice was challenged by a number of things. A couple of participants expressed criticism regarding the basis for doctors’ decisions. It was suggested that treatments might be experimental insofar as the doctor might not really know how necessary tablets are, but is still recommending them. Interestingly, this was mentioned by Richard, who also stated he would never question his doctor’s judgement about him needing a medicine (see above).

“I dare say a lot of it could easily be experimental, they could turn round and say try this, probably feeling but not saying, chances are it is not going to do you much good, but it is better than nothing, you just might...”  
(Richard)

Narrowly formulated, dogmatic reasoning about diseases influencing the advice that conditions needed to be treated with medicines was also criticised by participants. Notably, these examples were centred on treatments with statins against high cholesterol. Alfred, who was diagnosed with high blood pressure during a stressful time at work and has since tried a number of different tablets, is content with his blood pressure treatment but does not like his doctor’s persistent suggestions that he should take statins too. He has discussed the matter with his friends, and they share his view.

“Every time you go they try and push statins and I am very sceptical about it. [...] Going to the doctor’s nowadays is a bit like going to a dodgy MOT place where they will search and search and search until they find something wrong with you and then they can, they can you know find a drug to give you to sort out that problem. And as I say I am not the only one that thinks that.” (Alfred)

In response to my question about other possible sources of information about medicines, information leaflets in medicines’ packages were brought into the conversations. Participants’

views of the helpfulness of these leaflets differed – some said they always read them and others made sure not to. The former group wanted to read up to find out how the tablets worked so that the medicine could be used optimally and also prepare themselves so that they would be aware of their own positive and negative reactions to the treatment. Those participants that despised the information leaflets did so on the grounds of them containing too much information about unlikely events. Reading them, you might get afraid of side effects and start looking for symptoms. Michelle, who had experiences of both physical and mental suffering, did not want to be reminded of more health problems possibly being caused by the medicines. Paul, who was experiencing a period of skin irritation that he suspected could be caused by the medicines, still thought the lists of potential side effects were too detailed to be helpful.

“No, that’s fatal I think. Because you can get yourself all wrapped up in looking for symptoms, looking for side effects.” (Michelle)

“I mean I think we have perhaps got to overkill now of what you don’t do and what you do because I think the drug companies are terrified that if they don’t tell you, like one in ten thousand, you might get this, you might get that.” (Paul)

Internet as a source for information about medicines was also brought up in the conversations. The predominant opinion was that it is unreliable – anyone can post their thoughts and therefore it gets out of proportion. Anthony had built his knowledge about medicines and their effects from being attentive to his own health, reading books about medicine, asking doctors and also helping out at a community health centre. Paul and Holly both had experience of learning about managing practical aspects of other conditions from sharing experiences and advice on online forums, but when it came to CVD risk they did not think the internet was a good source of information.

“I won’t go on the internet; I think you get too much information on the internet.” (Anthony)

“... what you know I am certainly not going to go away now and Google it, in fact I think that is the worst thing you can do personally, because you get so many conflicting messages I think you come off Google more concerned than when you went onto it.” (Paul)

“You will get them saying oh you know you have got to try honey! So many teaspoons of honey a day and it will cure your high blood pressure and all this. And I mean honey is very good for you, I like honey but it has never done anything for my blood pressure.” (Holly)

Participants were concerned about the quality of medical information and advice. Most of them preferred sources that are controlled by experts – getting advice direct from your doctor or pharmacist about your own condition and the medicines you have been prescribed. However, too much detailed medical information, such as data about rare side effects, was regarded as possibly fabricating symptoms. On the other hand, information from one’s doctor – albeit also based on average results from large groups of people – was seen as important to act upon.

#### *5.7.2 Personal representations of the need for intervention*

In addition to giving the above reasons for accepting their doctor’s advice about addressing the high blood pressure, participants shared their own arguments for what should be done in terms of treatment. Again, examples of when it is necessary to act upon the CVD risk were mainly related to high blood pressure while cholesterol seemed a less strong reason to take action. Many stressed individuals’ responsibilities in terms of prevention of future problems. Participants gave examples of what they do themselves and also how ‘people in general’ might behave.

First and foremost, participants said, it is important to do *something* to lower the blood pressure and contain the risk. Taking action is important, both for participants like Paul who was not especially frightened by the diagnosis and for people like Joyce who found it upsetting. Nathan had even been sceptical of the initial information that his blood pressure was high, but had later come to agree with the doctor’s conclusion that medicines would be of use to him.

“I have no problem I mean, certainly at that stage I could see that when the doctor said; your blood pressure is now beginning... It wasn't extremely high, but she said I am the sort of person, who says right what are we going to do about it. And if that is what it means, taking a couple of tablets, I have no problem with that.” (Paul)

“I don't take medicines because I want to; I take them because I have to.”  
(Joyce)

“A lot of people put it in the hands of fate; well I’m a bit more proactive, I try and do something.” (Nathan)

No-one said the diagnosed CVD risk could be left without intervention, although some initially wanted to find non-pharmaceutical ways to manage it. Participants referred to general wishes not to take tablets unless it was absolutely necessary, and also gave more specific examples of why one should be restrictive with medicines. Many described aspects of their lifestyle as helpful in maintaining health. Walking, yoga, running, going to the gym, staying away from fatty foods and cutting down on smoking were put forward as examples. Albert had been diagnosed with high blood pressure and high cholesterol but did not experience any problems with his health at present. However, he put his current use of medicines in relation to a possible future need for effects and took this into the equation when he considered his tablets.

“I would say on balance you know the less I am taking the better because one day I might really need to you know and if you are starting from nothing then it's easier to ramp up obviously.” (Albert)

In some contrast to the reasons shared for not wanting to use medicines, participants had come to the conclusion that they ‘had to’ do it anyway. The necessity of addressing the blood pressure was emphasised by some participants via statements of it being ignorant to not follow the doctor’s suggestion about treatment. In the following quotes, Joyce and Rose – who have both been very healthy though their lives – point out that if a doctor says medicines are needed, that advice should be followed. James agrees, with a little caveat.

“I think if you have to have them, then take them. That is the advice from the GP; don't suffer unnecessarily. And some of them are essential, so therefore you are very foolish if you don't take them.” (Joyce)

“Yes, I mean I would take tablets if they say you have to. You know, I do know people who won't take them, and I think that is a bit silly if they know that they are going to do you good.” (Rose)

“Yes, it is my own will to take them, and I believe what he [the doctor] is telling me is true. In a fashion.” (James)

The personal conviction that one *has to* do something about the blood pressure strengthens the sense of participants perceiving an association between being at risk for and actually

experiencing an outcome. Actions thus appear to be based on the conclusion that if you have high blood pressure and do not treat it, you can or will die from a heart attack, and the tablets will prevent that. The notions that CVD events may happen despite treatment, or that one can have elevated biomarkers without suffering from the associated events, are not discussed by participants. An alternative reason underpinning the conclusion that medicines are needed, other than the necessity spurred by envisaged severe illness, could be a reasoning based on ‘might as well’ – that the medicines might be beneficial and are at least not doing any harm. However, although some participants found the risk condition quite undramatic, they wanted their tablets to help manage it. Patients’ anticipations of effects of medicines will be explored in detail in the second theme, which is presented in chapter 6.

The necessity of treating high blood pressure was expressed unanimously by participants in this study, albeit with slightly different causes given for why. In the case of elevated cholesterol, their views about the need for statins were less consistent. Through examples based on their own or other people’s thoughts, participants indicated that statins are sometimes more contested in terms of the underlying reasons for prescribing. Here, influences from prescribing guidelines and marketing of medicines were mentioned in addition to personal views regarding the need for medicines. Statins appear to be ‘less necessary’ than medicines which target high blood pressure. One example of this is Alfred’s comparison with a questionable MOT garage (see above), and another is given by Holly who had to convince her husband to take his tablet every night:

“I mean I fight with my husband because he won't, he wouldn't take one of his tablets and it is a cholesterol tablet. You have to take it, and I fight with him, when he first got it you know. One tablet a day, one a day!” (Holly)

Once medicines are accepted as necessary, which they were in some way or another among all participants in this study, they are to be used to a person’s best ability. This means reading up about the tablets, being aware of your experience when starting to take them or making changes to a treatment, and feeding this information back to your doctor if anything needs to be altered. Confusing stories about medicines in the newspapers or on the internet should be discussed with the doctor before you decide to change anything yourself, as explained by Rose who has slightly elevated blood pressure and cholesterol. Perhaps unsurprisingly, participants that described high trust in their doctors’ knowledge regarding the need for medicines also stressed the responsibility to involve him or her in further decisions about the tablets. Tobias, with a

history of severe heart-related illness but a very calm outlook on health and medicines, also points out that it is possible to be attentive to changes in the need for medication without getting worried about it.

“... or statins wonder drug, you know, it is, so... But I don't think you should go on what you read in the paper like that, it should be, you should discuss it.” (Rose)

“If something takes place and you get worried, that's all right. And if you get sick, you must worry about it, you must take medicine, go to the doctor, like this, you can't say I don't mind anymore, I am sick so I don't mind, I'll be all right. That is again wrong. You must take some action about it. But not worrying about it.” (Tobias)

However, a few participants had decided to disregard the instructions about how to take the medicines and instead devised their own routine that suited their daily activities. For Norman, this was a way of not giving in to medicines as a sign of old age, and for Gerald who was in his eighties and struggled with memory problems it was a strategy to remember the medicines and then focus on more important things.

“Although one of them says to take it on an empty stomach, from what I can remember one says take it at night and the other one says take it in the morning and after a meal. So I just pop the lot in one go. And as long as I have eaten something it's usually ok. [...] If you read the instructions I have to take one pill at four different times of the day and not drink, well then life is not worth living is it?” (Norman)

“So usually I take most of them in the morning and then those two, the warfarin, about six o'clock at night. The other I take first thing, you're not supposed to take them all together but it gets it out of the way.” (Gerald)

Aside from using medicines, changing your lifestyle or maintaining healthy habits also formed a large part of participants' descriptions of actions prompted by being diagnosed with high blood pressure. Some participants told me in critical words about friends or “other people” that just took tablets and did not engage with other efforts to stay healthy, or even used tablets as an excuse to eat unhealthily.



“I had a friend who was naughty because she would be out and having fatty things and she said oh it’s great when you are on statins, you can eat what you like. I said well you can’t really, you shouldn’t be. [...] It is very wrong if people are being given medication for things and they are still over-eating and not exercising. I think that is awful, I really think.” (Rose)

Nathan’s account of how he came to the decision to use medicines illustrates how medical information and one’s own views might be combined. He described how the doctor’s risk calculation computer software had indicated he was at risk for developing heart problems within the next decade, and how he has tried to reconcile that with his own healthy lifestyle:

“You know to say I have 20% chance of having a heart attack by the time I am 65, well not if I run 4 or 5 miles every day and eat healthily you know so, I don't actually necessarily believe what they are telling me is true.”  
(Nathan)

Many of the accounts of action taken by participants in response to the high blood pressure diagnosis were given with great emphasis. Patients’ responsibility for partaking in treatment and doing your best in terms of lifestyle habits described as healthy was a recurring and prominent feature in the interviews. Whether it was motivated by the fear of what might happen if they did not treat it, by wishes to promote one’s health or just because your doctor said it was necessary – engaging with the management of your CVD risk is the “right thing” to do.

### *5.7.3 Concluding the subtheme*

Despite the apparent principal difference in approach between patients and health care professionals when it comes to explanations for high blood pressure (lifestyle used as example by patients but this explanation is not supported by how health care professionals act), medicines have an undisputed place in both sides’ strategies for what to do when the blood pressure is high. Patients emphasised their individual responsibility for engaging with actions that will lower the blood pressure, and active intervention with both medicines and lifestyle changes was favoured. In terms of cholesterol as a risk factor, it was much less prominent in participants’ accounts of CVD risk.

## 5.8 Cohort strategies

Alongside the highly personalised ideas about causes for and consequences of the identified risk and the individual responsibility for partaking in interventions, indications of awareness of the large scale aspects of CVD risk management treatments were also present in participants' accounts.

### *5.8.1 Individuals and populations*

In a few interviews, the mentioning of age as a cause for high blood pressure or cholesterol was combined with the reflection that most people in one's peer group were suddenly on medication for CVD risk-related conditions. This normalised the diagnosis, and allowed for the sharing of information and experiences within groups of friends or work colleagues. James and Albert, who had been diagnosed at routine examinations and then had medicines prescribed to manage CVD risk factors, suggested that people might more or less routinely get medicines prescribed at a certain age.

“you know all the lads I speak to at work, soon as they came about and I've read in the papers many times, you know doctors are putting people on statins as soon as you hit that sort of bracket.”

*And why do you think that might be?*

“Well I think, unless they didn't go for any check-ups and they automatically got put on statins because the doctors say so, that's to each individual.” (James)

“people are telling you often enough that high blood pressure as you get older does lead to risks so it doesn't seem an unreasonable thing and erm... I suppose most of my contemporaries are also gobbling the same things so...”  
(Albert)

In some senses, though, participants seem to set themselves apart from others. This again emphasises that for patients, an individual perspective on health and medicines is always present. One example is references to “older generations” that will uncritically accept doctors' decisions, as opposed to the participant, who would always question if the medicine is needed. Albert has reflected on the fact that there are incentives for GPs to diagnose more patients with high blood pressure, but he still trusts that his diagnosis was the result of a personalised risk assessment. Rose tells how simple and available the QRISK test is, and that doctors base their

decisions on it – but trusts the recommendations about blood pressure medicines and statins to be suited to her personally. The link between being part of a cohort and getting personalised medical advice seems to lie in having a good relation with one’s doctor.

“I mean I have no reason not to trust him as a competent doctor, and I do know from other friends who are in the business as it were that you actually sort of can tick a box these days by putting people on some of these things but... I will give him the benefit of the doubt he is not just doing it to get his numbers up.” (Albert)

“she said now we would do this test with you, we wouldn’t just give you them [...] but she said you can do it yourself really it is on the internet where they take into account what your parents died of, your weight, you know different things like that” (Rose)

### *5.8.2 System critique*

Although the participants in this study were all using medicines – most of them with the understanding that their CVD risk meant they had to – some criticism towards the prevention approach was voiced. The principle of prescribing to individuals on the basis of evidence of effects in populations was questioned both in terms of the accuracy of the risk assessment and the possible outcome of treatment. In addition, a couple of participants expressed criticism against the idea of widespread pharmaceutical intervention to promote health. Health checks were seen not so much as opportunities to identify and address things that could potentially be problematic in the future, but instead as doctors looking for diseases. Connections were also made to the higher levels of health care provision, for example by Samuel who in addition to describing his own thoughts and views about medicines also discussed the idea behind how the NHS aims to promote health and prevent disease. Another reflection on the systems behind the preventive strategies was made by Nathan, who referred to his career in engineering as the reason for why he pondered over the statistical aspects of CVD risk management.

“Doctors are governed; they have got a guideline and have to follow it. They are officers for the government; to apply its policies. [...] Well that goes back to the government, the reasons, the policies, each government has its own set of rules of budgeting, that’s the result of it. So it’s about money.” (Samuel)

“so they hit you with these statistics and whether they are true or not I don't really know, I mean there has got to be some evidence to show that, you know, that could be the case... but are they supplied with enough information? I don't know. [...] it might be true for some individuals, you know, but you have got to look at other factors as well.” (Nathan)

## 5.9 Discussion

Having presented the first main theme, I will now review my findings in relation to literature on patients' understanding of risk management and medicines. The discussion is structured along two topics that condense the findings: participants' individualised interpretation of the CVD risk, and the imperative to take action to manage it.

### 5.9.1 *An individual interpretation of risk*

Being diagnosed with CVD risk in the form of high blood pressure was unsettling to some participants because of the image of the condition as something that could shorten their life. There was also an element of surprise that the blood pressure was high, which added to the unpleasantness of being diagnosed. Notably, participants' examples of how it was to find out about CVD risk focused on blood pressure as a risk factor, whereas cholesterol did not figure so often in these descriptions. With regards to the event of being diagnosed, Nettleton outlines the many ways in which biomedical diagnosing shapes patients' understanding of conditions.[49] Getting a diagnostic label on something that is 'wrong' may validate and explain symptoms of illness as legitimate diseases and enable patients to access services. In a wider perspective, diagnostic classification provides a system for the allocation of health care resources, and is a central feature of medical authority. Although the majority of my interview participants were at low risk and had not experienced any symptoms of CVD, they interpreted the diagnosis as a sign of imminent disease. In high and low risk participants alike, the diagnosis led to engagement with behaviours aiming at containing the risk – many of which were based on the doctor's approach to risk management. Thus, the concept of getting diagnosed may not rely on symptoms to have an impact on patients' understanding.

An important feature of primary preventive CVD risk management is indeed that the risk factors are identified by a doctor at an asymptomatic stage. This invites suggestions regarding the impact of the process of examination and diagnosis on patients' understanding of the

condition they have. In a study of patients' experiences of CVD risk screening, Saukko and colleagues [180] suggest that the risk assessment in itself frames conditions as naturally defined, when it in fact rests on socially negotiated thresholds. The levels of high blood pressure and cholesterol that are considered high enough to be a reason for pharmaceutical intervention are not determined by clinical or symptomatic signs but decided based on statistical exercises in clinical trials in combination with cost-effectiveness analyses.[61]

Dumit [135] offers a suggestion for how a general, asymptomatic state of elevated biomarkers might get to be interpreted as a personal disease or condition. He suggests that risk management medicines have been marketed, and are thus known in the social world, on the basis of everybody's potential to be afflicted by disease. Emphasis is placed on the presence of symptoms or signs that can underpin a diagnosis, while weak causal associations and predictive values of treatment are obscured. Decades of this type of communication about medicines has established the idea that health-related issues are medical problems and that pharmaceutical intervention will be beneficial. This reasoning could explain how participants that reported themselves as being in good health and telling me how they looked after themselves still found it plausible that they needed medicines. The identified signs of disease might introduce an element of uncertainty into the image of one's health.

Participants expressed an individualised understanding of their CVD risk diagnosis. Although many referred to generalised causes for their own elevated risk (age and lifestyle) they did not see themselves as part of the cohorts that are the targets of large-scale prevention. Their own high blood pressure was described as brought on by some particular reason, rather than as a function of combined risk factors. As expected from reasoning centred on the individual, the imagined effects of CVD risk were also pictured in terms of threats to the person. When picturing the possible consequences of for example high blood pressure, both primary and secondary prevention patients refer to cases of fatalities or disability in their immediate family. They mention not wanting to die or fear of getting a worse quality of life when describing what might happen. The use of personal experience or knowledge about particular cases rather than numerically supported evidence is called heuristics, and is a classical way to make sense of things that are difficult to conceptualise, such as determining the value of future health interventions or medicines.[181]

Hence, participants apply the arguments and endpoints that underpin prevention strategies on the population level onto their own personal situation. This demonstrates that one of the

defining features of primary prevention in CVD risk management is eliminated from the reasoning, namely the weak causal associations between elevated biomarkers and cardiovascular mortality.[124,182] A result is that for patients, a personalised, black-or-white interpretation of CVD risk management comes to dominate over the grayscale of risk reduction that underpins policies of disease prevention. Notably, my impression from the interviews was not that the understanding of CVD risk as rather closely associated with cardiovascular events and mortality had frightened participants into taking medicines. Instead, it shaped their view of the value of risk management. The result is a distance between ‘the personal risk people perceive’ and ‘the clinical risk that is reduced by medicines’.

### *5.9.2 Taking action – using medicines*

The perceived connection between the CVD risk and aspects of their own life probably contributes to patients’ feeling that it is their responsibility to do what they can to control the blood pressure and, to some extent, cholesterol. In contrast to other risk conditions that might be ignored with the thinking that ‘it will not happen to me’, a diagnosed CVD risk seems to be interpreted as important enough to intervene against.

Advice from medical professionals, in particular GPs, about treating the CVD risk with medicines was accepted by all participants in this study. Although having and expressing their own thoughts and opinions about using medicines, patients ultimately adopted the GP’s view that treatment would be beneficial. Those that initially were hesitant towards starting to take medicines transitioned to acceptance of taking tablets every day. Even those that did not fully believe the risk calculation, or felt convinced about the benefit, thought it safest to start taking the medicines anyway. Patients in the low and high risk groups used similar reasons in explaining why they had chosen to take the tablets, indicating that even a moderately increased risk for a CVD event is understood as a strong cause for treatment. A recurrent impression of mine from the interviews was that a diagnosed CVD risk becomes somehow separated from the person, and instead becomes the professionals’ domain. Such a process could lead to the patients perceiving that their own opinions on using medicines are no longer fully valid.

The doctor’s recommendation was interpreted by many participants as personally adapted advice rather than application of a guideline on a target population. Even those that brought up population-level aspects of risk management strategies in interviews (such as incentives for diagnosing and risk assessment algorithms) stressed that their doctor gave them personal

advice. Here, as in the case of interpreting the relation between the CVD risk diagnosis and possible outcomes, the denominator used by patients is again their own singular person.

Regarding benefits from risk management medications, there was a difference in how treatments for blood pressure and cholesterol were perceived. All participants had incorporated anti-hypertensives into their daily routine, whereas the use of statins divided the group. The difference in how the drug classes are valued might be explained by where statins are in their life-cycle; they were introduced to the CVD risk management arsenal in the 1980's and thus have a shorter history of use. Recently expired patents on several statins make producers seek for expanded areas of use, leading to professional debate and presence in the public sphere (see chapter 3). Efforts to clarify aspects of efficacy and safety might mitigate the ongoing controversy.[126,183] Increased familiarity or socialisation with time – perhaps aided by the increasing reliance on pharmaceuticals in health promotion – may lead to statins eventually becoming as accepted as anti-hypertensives currently are. Another possible explanation for the difference in perceived necessity between anti-hypertensives and statins could be the availability of possible alternatives: alongside statins are multiple food items that are marketed on the basis of their cholesterol-lowering properties,[136] whereas no such specific products are present for high blood pressure. These questions would need to be addressed in further studies of patients' perceptions of CVD risk management.

All participants in this study had made the choice to take medicines for their blood pressure – sometimes as the only way to address it and sometimes as one of several efforts to maintain or improve health. Some were also using statins. Although being diagnosed with high blood pressure was a noteworthy event, taking medicines to ward off the anticipated effects was not described as particularly dramatic by participants. In their examples of what they did to decrease the risk that comes with having high blood pressure or cholesterol, taking tablets blends in with examples of lifestyle behaviours such as eating well and keeping active.

## **5.10 Summary**

Personalised causes for CVD risk were given as explanations for high blood pressure or cholesterol, and reasons for intervening were likewise expressed with an individual focus. The indications of a close relation between high blood pressure and serious outcomes are far away from the arguments that form the logic for a population strategy in CVD risk management;

treating cohorts to achieve a small average risk reduction and eventually influence overall mortality in the population.

People made sense of the unsettling diagnosis by using personal experiences and expert advice. Both these things contribute to the dissonance between the risk that patients perceive they are facing and the ‘real’ risk that is targeted in preventive interventions. The medical context that surrounds the introduction of the concept of CVD risk might lead to a medical method of action – in the form of taking prescribed medication – being favoured as a strategy to contain the risk. However, in spite of placing CVD risk in a context of dramatic personal illness, the medicines taken to avoid it are, or quickly become, an undramatic part of everyday health work. How this happens is explored in the next chapter.



## Chapter 6

### Findings II: Seeking stability

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#### 6.1 Chapter overview: the second theme

In the previous chapter I presented the theme that shows how patients perceive being at risk for CVD, drawing together aspects around diagnosis and decisions about interventions. Here, I turn to a discussion of how the management of that risk is experienced and evaluated. The second core theme arising from the dataset was that of stability of blood pressure and cholesterol as a central feature of participants' evaluation of the medicines they take to manage CVD risk.

#### 6.2 Seeking stability

To find out how effects from medicines were experienced or pictured by participants, I asked if and how they felt or thought the tablets helped them. Answers to these questions contribute to the understanding of patients' reasoning around conditions associated with CVD risk, by showing how management of the risk factor is put in connection with the outcome that is supposed to be prevented. The subthemes describe the 'continuous individual assessment' that patients were engaged in and the 'thoughts about future outcomes' they shared with me. Table 6.1 outlines the structure of subthemes and categories.

Table 6.1 The Seeking stability theme with subthemes and descriptive categories.

Seeking stability	Subthemes	Categories
	Assessment of present effects	Experiencing medicines
		Seeing results
		Interpreting strategies and effects
		Balancing the present and the future
	Thoughts about future outcomes	For myself
		In general

### 6.3 Assessment of present effects

Although most CVD risk management medicines are prescribed for the purpose of preventing future disease, they are also part of everyday life for the patient using them. As shown in chapter 2, a continuous evaluation of effects is an important part of how patients relate to medicines and form expectations about future outcomes. Experiences of illness and medicine-taking build knowledge about how to balance conditions and effects of treatments, and how these things can be fitted into daily life.[22,39,41,184] This subtheme shows which indicators participants used to assess effects, and their ways of interpreting what the medicines do.

#### 6.3.1 *Experiencing effects*

This category describes participants' assessment of the effects that medicines presently have on their bodies, on their health and in their lives. After the initial decision to follow the doctor's advice and try to use medicines to manage the blood pressure, a major influence on continued engagement with treatment is whether the medicines are seen as suitable for one's own body. The way to find out is by being attentive to your body when it tells you if the medicines are working for you; if they produce the desired effects and not bring about any unwanted changes. James, who has tried a few different medicines to get his blood pressure and cholesterol treatments right, describes how he has a routine of checking the information about possible side effects in the information leaflets and monitoring himself when starting a new treatment:

"I'm not just gonna pop them in my mouth and say 'that's all right doc', whatever the doctor gives you. I do my own little bit of read-up of them and see how I am, give it time to come on to me and then... I take the tablets and see how they are in the next few weeks, am I feeling all right? And if they're ok well then, yes." (James)

Other participants also conveyed how they evaluated the medicines by using their bodily feeling. Negative effects, or the absence thereof, helps in making this evaluation as described by for example Samuel who valued his own experience of health when considering his medicines. Paul, who had recently noticed a side effect from his blood pressure medicine, and Judy who compared the current treatment with the more tangible regime brought on by breast cancer, also looked to their previous experiences for evaluating the medication.

"Well I believe how I feel. Because nobody can feel the way I feel except me, ok." (Samuel)

“I suppose apart from literally this last two weeks where I have had to say, yes, my body now is telling me that there is something wrong. You know I started on some tablets, so for it to be a coincidence would be amazing.”

(Paul)

“I don't really think about it, I just take it in the morning, when I have my breakfast, I have not noticed any side effects it's a very, very, very low dose, so I don't know whether I am expected to notice anything.” (Judy)

Broad descriptions of how the medicines affected one's health were also present in participants' accounts. Some shared stories about side effects that had had effects on their daily lives and induced investigation and changes between tablets. The GP had been a reliable help in finding a medicine that was suitable. The feelings of being 'stable', 'in shape' and 'on an even keel' are not directly related to the CVD risk, but indicate that the medication prescribed as a result of specific risk factors can be perceived as having general effects on one's body.

“I just feel everything is like normal, if that's what it is. It's helping me that way, keeping everything on sort of an even keel if you like.” (James)

In a long-time perspective, the absence of problematic effects gives a sense of security even when frightening information about medicines comes out in the news. Both Fred and Stephen have had symptomatic health conditions for a number of years, and they referred to their history of taking medicines as a reason for not worrying. Again, the personal experience of a certain medication in your own body weighs heavier than data from large populations when it comes to patients' evaluation of their medicines.

“Yes the aspirin can cause all kinds, strokes and everything, so you do think to yourself 'oh' but then you think 'well I've been taking them for 17 years' so I just keep on taking them.” (Fred)

“I asked my doctor about that and he said 'look, do you feel all right taking them?' and I said 'of course' and he said 'well carry on then, don't worry'.” (Stephen)

### *6.3.2 Seeing results*

Some participants did contrast the treatment of their high blood pressure or cholesterol with other medical conditions where you can actually feel or see the effect of efforts to make it better, such as headaches, ulcers or cuts that heal. However, they had found ways to get indications of whether the risk management medicines were helping the particular risk condition. Immediate effects from blood pressure- and cholesterol-lowering treatments were readily described in terms of a controlled blood pressure or a cholesterol value within range. Similar descriptions were used by participants who were content with their medicines, like Alfred, and by those who had a more problematic relation to their health, like Michelle and Stephen.

“...your blood pressure is up and I think it was very high at that time, and then the drugs did actually bring it right down. And it seems to be fine now quite honestly so...” (Alfred)

“I was on a particular tablet and for 12 months, we tried to get it down. And it was sky high all the time. And we couldn’t get a hold on it. So they put me on a combination of three, apparently it’s very common, once you go on these three you come down. And I’m now on them three and it’s been magical, my blood pressure’s been down.” (Michelle)

“I couldn’t control my cholesterol because I don’t know what it was, he said best go on the statins and touch wood it’s been ok since you know. I take them every evening.” (Stephen)

Aside from seeing the blood pressure or cholesterol come down at the start of treatment, regular confirmations that it stays stable are taken as indications that the medicine continues to be needed and beneficial. Several participants told me they have got their own blood pressure machines and monitor themselves; as a way to check whether they have remembered to take the medicine or just because they got interested in measuring it.

“But with other medicines, like the problem with high blood pressure, you don’t always notice the effects quite in the same way but as I say I do monitor my blood pressure.” (Alfred)

“I check it myself yes. It is the way I remember if I take the pills or not.”

(Norman)

Blood pressure monitoring done at check-ups with the doctor, or in Fred’s case every day via tele-health equipment, also inspires trust, since it is interpreted as saying everything is fine in the body. The monitoring of risk factors was described by all participants as an un-dramatic, routine event. GPs that keep an eye on you by measuring and feeding back results also provide signs that the efforts to look after your blood pressure and cholesterol are worthwhile.

“Like in every February I get my annual test, round my birthday you know, going for my bloods and then I go back in two weeks after and you see how your blood results are, you see the doctor, and they tell you that everything was fine. You know, from the year previous, it’s come right down. They go back over the records.” (James)

“... and I have my checks every year and it’s always the same you know.”

(Judy)

“And I’m on this thing that has come out now, it’s on the telly, every morning I’m monitored. I’ve got to give me weight, so I need to get this thing to stand on, and then I get off that and the thing goes on my arm for the blood pressure. And that all goes through the telly, and wherever it goes after that. And that it tells you ‘your blood pressure is ok today, your other things are ok today.’” (Fred)

Some participants discussed the possibility of getting an additional confirmation of the effects of their medicines from a period of not taking them. In parallel to following the lowering and stabilisation of measurements when the treatment started, seeing the blood pressure or cholesterol go up as a result of not taking the tablets seems to strengthen the conviction that the medicines are really doing something. Such testing of effects was done either as an active decision to stop the tablets for a period of time to see what would happen or involuntarily, for example due to a shortage at the pharmacy.

“I mean I have a fairly sedentary, I work in an office so I am not running around and I thought ok, I am prepared to take the risk and I did, for a week I thought I will just see.” (Paul)

“... last time they did my pills I hadn't taken the statins for about a week because the local chemist here had run out, bloody hopeless they are, so when she took it I was 6.1. She asked me why, had I been eating fat, and I said I haven't been taking the statin for a week, so it jumped straight back up.” (Norman)

Participants evaluated the test by checking biomarkers or their general feeling. Richard, who did not have any experience of ill health, even suggests that the *only* way to find out what the medicines do is to actually stop taking them, but he does not want to test the effect.

“And I know if I don't take them I can feel something is not right in my body.” (Stephen)

“I don't know, how can I evaluate that because I can't turn round and say, if I stop taking those for 3 months then by now I would have been able to... because I don't stop them.” (Richard)

Throughout the interviews, two ways of knowing about effects from medicines were present side by side. Participants followed changes in the blood pressure and cholesterol, but they also observed how the tablets suited their bodies. The first of these methods for evaluation fits a biomedical description of CVD risk management, and might help patients ‘check’ whether the doctor was right in suggesting treatment. The second approach points to the importance of patients’ experiences, past and present, in evaluating the use of medicines.

“Well the external sort of demonstration of my life doesn't seem to have altered at all... the only way I notice the difference is the fact that my blood pressure has settled down and is you know, at a reasonable level now.”  
(Alfred)

### *6.3.3 Interpretations of the medicines' effects*

Since a core topic in this research project was how patients perceive benefits from medicines, I asked the interview participants explicitly how they felt or thought the tablets were helping them. In answers and examples that followed from such questions, participants referred to the immediate effects they had seen on their blood pressure or cholesterol. The fact that the biomarkers had come down and were controlled was turned into a description of the medicines fulfilling a specific task. Thus, accessible confirmations of medicines' effects – whether

provided by one's own blood pressure readings or mediated by the doctor at check-ups – help to define both the risk condition and the need for medicines to manage it.

In addition to assessing whether you 'feel ok' with the medicines, and in the absence of symptoms to be relieved, these confirmations became the sign that something was happening due to the tablets. One way of describing this was as the medicines 'doing their job' – indicating that management of risk factors is indeed seen as a distinct outcome of treatment. Nathan, who doubted the applicability of risk assessment methodologies to himself and made an effort to have a very healthy lifestyle, used the effects on his blood pressure and cholesterol as proof that he had really been at risk for heart disease and thus needed the medicines.

"I think because my blood pressure was so high, and now it is at a level... I think it proves itself that the medication is doing its job." (Joyce)

"I mean yes my blood pressure is down to normal because I am taking the blood pressure tablets so that is an indicator that they are doing something."  
(Nathan)

Another way of elaborating on the beneficial effects was to allude to the logic that they must be doing something good for you – just like medicines from which you actually can feel the effect. As in the case with the CVD risk diagnosis, participants accepted their doctor's approach to risk management and therefore concluded that since they had been recommended and prescribed, the medicines would be helpful. Fred relates his idea of effects from medicines to his tangible heart conditions that were the need for heart surgery in the past, whereas Paul who has very little experience of illness draws on how other medications work.

"Obviously, I've had the heart problems, I've had the bypass 17 years ago so I think if he's given me them at least they must be doing something there, to make sure everything is ok. That's the way I think about it." (Fred)

"I still can't believe that you take a tiny little white thing like that and it can have such a dramatic effect, that is beyond my comprehension but we all know if you have got a headache you take an aspirin, it has an effect, so, I know their effect and obviously you wouldn't be given them if they didn't."  
(Paul)

However, the view that the medicines are beneficial and therefore should be taken was not unanimous. A couple of participants used examples from their own or other people's lives to show how experiences could make you question the necessity of medications. The first example is from Samuel, who realised that he could manage his blood pressure and diabetes without medicines during a time when he could not get hold of any, even in a stressful situation. Despite this, he returned to taking the tablets when he could, stating his respect for science as the reason for deciding beyond his own experience. The second example was shared by Fred, who pointed out that he knew of people that chose not to take medicines – sometimes for good reasons.

“Roughly between four and six months I didn't take none of these, because simply I ran out, I was in a war zone where nothing was available to me. But I still managed, and I found my health better off without it. I just got on, there was more exercise, and watching what I ate, my food you know. And that somehow, it worked. At that period, although I was stressed because of the war, but my blood pressure was ok. And my diabetes, absolutely all right. So I didn't see why one should take these things. [...] No, I don't think they're doing anything for me right now but they might prevent things ahead. Yes, that's the reason I take them.” (Samuel)

“I know a lot of people, doctors give them tablets, but they won't take them. A good friend of mine, he won't take them, and he reckons he feels better! He said, you know, where he lives, to get to the bus stop you've got to walk over a hill. He said 'for years I've struggled, getting over that hill, but since I packed those tablets in I'm like a young 21-year-old, walking over there.' So then sometimes you think, are these tablets doing you well or are they?” (Fred)

#### *6.3.4. Balancing the present and the future*

As a consequence of the perceived or anticipated benefits and experiences of or worries about negative effects from the medicines, participants had several types of information that could be taken into account when evaluating the tablets and making decisions about whether to continue taking them. Information from their doctor was one trusted source, but experiences make up an important part too. The balancing of disease risk against possible benefits and harms from medicines is a central feature of risk management prescribing, but might be done



differently depending on if it is done from a patients' or a clinician's perspective. The following quote from Albert, who takes blood pressure tablets as well as statins for his cholesterol, sums up the challenge of risk management prescribing, and shows that also patients can have a very good understanding of this medical challenge:

"I would like to think I am not taking anything that is unnecessary as it were... I suppose it is what you are asking and how can I answer the question; what is the balance between alleged side effects or you know, the doubted benefits of a stable blood pressure, I don't know. [...] I appear to be suffering from no side effects, there is an alleged tangible benefit, so I'm happy to carry on." (Albert)

After hearing participants describe their own experiences of ill health and use of medicines at the start of each interview, I used their examples in questions about if and how they combined the 'pros and cons' with the medications. Prompts related to these questions included which aspects they took into account and whether their opinion had changed over time. I was interested to hear what went into the balancing from participants' point of view, and also what type of language they used to describe CVD risks, effects and possible outcomes.

As seen in the quote from Albert above, some of the participants in this study sided with a medical description to illustrate their reasoning around positive and negative short- and long-term effects. Others extended it by using hypothetical descriptions or including previous experiences of using medicines when describing how they did it. Nathan describes how he wants to understand the medicines in much the same way as he wants to understand how other things work. Michelle and Judy compare their blood pressure treatments to having used other medications, causing tangible effects and side effects.

"I mean even if you had a slight negative effect in some way... I think you have got to find out, you know, by asking the doctor, what is the balance because even though in the, well say in the long term living with that negativity... might not be as bad as having a problem for which the drug you are taking is supposed to prevent, so yes you have to understand. Well for me anyway, just for my peace of mind." (Nathan)

"I think it was the morphine that kicked it over the edge. Had I not gone on the morphine I think I had just trundled along and not thought about

medication because my life was... it was such a norm for me to take it.”

(Michelle)

“Compared to what I have had before, there is absolutely no impact whatsoever, which is good.” (Judy)

After incidents with experiencing side effects from treatments, participants tell me how they had become aware of what can happen when you start taking a new medicine or change the dosage of an old one. This has prompted an apprehensive attitude when a change is suggested, and there are several ways to try and find out as much as you can beforehand. Here, other people’s experiences add to one’s own knowledge. Information is shared with friends and family, and explanations from the doctor are balanced with one’s own active testing of the medicine and thoughts about future outcomes. Anthony and Alfred had experienced some unpleasant side effects from medicines and medical procedures in the past, and Paul was acutely aware of how present problems needed to be balanced with future outcomes.

“... so if I get a new medication, I will question what it does and what it is supposed to do, and as long as you have got that in your mind you can sort of go along and you toe the line, that has worked for me. But it is only through questioning.” (Anthony)

“But it wasn’t until I spoke to other people that I realised it was the felodipine that was doing it.” (Alfred)

“It’s a risk assessment in effect, and as I say I know whilst it is sometimes unbearable, uncomfortable, irritating this dermatitis... As I say, with being a lay person, I think to myself well that’s never going to kill me, why take the risk? And say ok, the blood pressure may, I could have a stroke.” (Paul)

Participants also mentioned more general thoughts on the concept of using medicines that were included in the balancing. Having to take medicines is framed as both socially and personally undesirable – for example by Joyce who describes how some people use medications as a reason for giving up on trying other ways to stay healthy. Examples of the individual disadvantages included thoughts about whether using medicines for a long time has negative effects aside from those that are immediately discernible; damage might build up over time, which is of great concern to Stephen who worried quite a lot about being on life-long medication. The amount taken every day was also of concern, and low numbers of tablets or

milligrams taken every day were given as justifications of participants' own use of medicines being acceptable and manageable. From a social perspective, participants mention 'other people' who unfortunately have to take many tablets every day. Their own medicine-taking was justified by referring to the diagnosed CVD risk; many participants stressed that they did not particularly want to take tablets, but did so because they had to.

"I think the less tablets you can take, the better to be honest with you, because everything is going to have a side effect a bit isn't it?" (Rose)

"What I worry about is the side effects on your internals, kidneys and especially your liver. With this chemical compound that I'm taking, that it won't cause me jaundice or things like this. When I'm taking the vitamins I know they're not doing any harm to me but when you're taking chemical compounds every day, twice a day, 365 days a year you get to think well, is there a build-up of all this chemical going round in my body?" (Stephen)

"people I think a lot of people take a tablet, sit down and think well that's my life over, you know if they are taking medication which I could have done, I am just going to sit here now and you know I am taking tablets and that's it. You can't do that, you have to try and continue as best you can."  
(Joyce)

### *6.3.5 Concluding the subtheme*

Participants' assessment of effects from the risk management medications comes together in their conclusions about whether the medicines work for them – if they bring the blood pressure or cholesterol down without causing unpleasant side effects. Testing, visualisation and physical experience of effects build patients' knowledge about how the medicines work and what they achieve.

In relation to the unpleasant experiences surrounding the CVD risk diagnosis (see section 5.5.1), visual and numerical repeated proof of one's blood pressure being stable seems to reassure participants that they are managing the condition. Those that were not worried by the diagnosis felt they had taken steps toward prevention. Accessible and practical approaches to depicting the risk condition appeared to be strong motivators for treatment.

Throughout this subtheme, the user of medicines is present as an active agent, testing and evaluating to assess the medications. This role, also exemplified by the feeling of responsibility to take action and control one's risk, exists in parallel to a more acquiescent one that trusts and follows the doctor's advice (see for example section 5.7.1). However, both types of reasoning still rely on two assumptions regarding CVD risk management: the applicability of medical evidence onto oneself is taken for granted, and CVD risk is regarded as serious and potentially life-threatening. Participants' acknowledgement that the initial decision to take medicines was not to their own liking or choice, but was made out of necessity, shows how the view on CVD risk and its management is negotiated with personal opinions about medicines.

## **6.4 Thoughts about future outcomes**

To find out how participants pictured the long-term preventive effect from CVD risk management medicines, I asked which results they hoped the tablets would produce and whether they felt it was worth the effort to take them every day. Both high-risk and low-risk participants referred primarily to the immediate effects on the risk factors – as shown above, stable blood pressure and cholesterol values were seen as treatment success – but thoughts about future outcomes were also present.

### *6.4.1 Effects for me*

As shown under the sub-theme 'Contextualisation' (see section 5.6), part of participants' understanding of their high blood pressure diagnosis was that it would lead to severe consequences. In response to my questions about whether they felt or thought the medicines were effective not only in controlling the blood pressure but also in preventing heart attacks or strokes from happening in the future, participants combined the generalised statements about protection from disability and death with ideas based in experience and personal understanding.

The balancing of tangible effects at present with hoped-for prevention from serious illness in the future was mentioned by a few participants. In their examples, they used references to their presently controlled blood pressure to explain what the medicines would achieve in the long run. Both Michelle and Nathan, who had very different backgrounds in terms of experience of ill health, made a direct connection between effects now and outcomes later.

*And even if you don't kind of feel the effect of the blood pressure tablets, do you trust that they can help you?*

“Yes I do. I hope they are. Yes, because they've lowered my blood pressure so therefore I would imagine I'm less likely to have a heart attack or a stroke. So that's the bottom line really.” (Michelle)

“I mean I am you know... quite willing to take them just to prolong my life, you know, stop any serious problems.” (Nathan)

Influence on the eventual outcome was not elaborated on as much as the visible, accessible sign that the blood pressure has come down. However, most participants indicated that they trust that the tablets play an important role in preventing serious events. The following quotes are a reminder of how the CVD risk diagnosis is perceived, and also show how effective medicines are seen to be for saving one's life. Here, Norman relates to his previous angina problems whereas James puts CVD prevention into a community perspective. Taking medicines to manage the risk is presented as a case of either-or, rather than shifting probabilities.

“Well you know as I said before you don't have a choice. Do it or croak. So you have got to take them at their word. I mean, you hear about bad doctors and they prescribe the wrong drugs and things like that but at the end of the day, you have got to feel these things out for yourself haven't you.”  
(Norman)

“... and being in the funerals [running a funeral home] I know it's nowhere near the average. My wife was only 59, and I can go to the cemetery and I know more people there than what I do out in the streets. And I look at the ages: 36, 24, 48, 37 when I go to her grave and as I go around I think 'there but for the grace of God', so I keep taking the tablets.” (James)

Participants' reasoning about medicines and prevention was related to different aspects of health. Some wanted to ensure longevity, like Nathan who made sure to live healthily with a lot of exercise and good food. Those that had young children, like Michelle and Samuel, mentioned capacity to take care of one's family. Holly, who had a lot of experience of health problems but also had worked out how to manage them, wanted to be able to enjoy life. This

highlights some of the expectations that participants place on CVD risk management, and also points to the individual as being the centre of interpretation.

“I would prefer not to take anything but it’s medicine, it keeps you alive so yes.” (Nathan)

“give it me, I don’t care what it is, as long as it keeps me standing for my kids” (Michelle)

“I have to live, not just for myself. I’ve got very young children as well. So I have got to look after myself to be able to look after these people who need my help. Now, if I was just a person on my own, probably I wouldn’t care that much. So I have to look after them. In order for me to look after them, I have to look after myself. And that’s my philosophy about the whole thing.” (Samuel)

“I value my life too much. I value my quality of life too much. Because I do know if I didn’t take my arthritis drugs I wouldn’t be able to walk, I do know my psoriasis would just be horrendous, but then that is just a part of life, but my asthma would bother me, my high blood pressure would bother me, and life is for living [...] We live every day we possibly can, you know to the best of filling in every minute of what we want to get done.” (Holly)

#### *6.4.2 Effects in general – CVD risk management as a principle*

This final category entails the descriptions of how the strategy of CVD risk management was perceived by participants. As shown throughout the previous display of findings, participants used multiple sources of knowledge when making decisions about their own use of medicines; most notably personal experiences and information shared by their doctor. Similar resources were used also in participants’ appraisal of prescribing and its outcomes on a more general level.

Opinions on cohort strategies for disease prevention revealed some criticism towards the current strategy of extended prescribing. Alfred had declined the addition of statins to his blood pressure treatment, and describes how a focus on more medicines could challenge the trust in doctors. His complaints focused on statins, whereas Samuel questioned pharmaceutical intervention in general.

*“Well I don't know, I think, like this business with the statins I think, I feel sometimes that they can be a bit blinkered, that they tend to be looking down a sort of narrow avenue, rather than looking at the wider picture. I don't know whether that's right or wrong but that is what I generally feel.”*  
(Alfred)

“people like myself should be encouraged to, instead of all this stuff which is too expensive and they might have side effects, to encourage to do more things [...] how to eat, dieting, exercising, stuff like that. But the doctors don't do that, they immediately prescribe these things. [...] All this which I think is expensive, and also probably they're not working as good as they may think, the doctors might think.” (Samuel)

However, some participants expressed examples of how risk management medicines also have a place within the wider context of health promotion. These accounts related to the person's own health and perceived outcomes, as well as hinting at the principle behind large scale prevention. Paul, who is in the low CVD risk group and manages his blood pressure with a singular type of medication, does not see the daily tablet as infringing on his life, and Nathan has also come to see the medicines as yet another part of his efforts to stay healthy. So does Joyce, who refers to her and her husband's situation describes their medicines not as an indicator of illness but as a way to health.

“No-one is asking me to do much, they are not asking me to run a marathon every day, are they? It's simply take these tablets so... I would do it.” (Paul)

“We consider ourselves very lucky that we have got to this stage and we are still in our, you know, reasonably healthy with the help of medication.”  
(Joyce)

“So I don't believe the risks were there but having said that... It is beneficial obviously to be more healthy so if you can lower your blood pressure down, to a moderate level, that in the long term should benefit me, I recognise that that is... I still don't like taking the drugs, but I am willing to do that for the longer term health benefits.” (Nathan)

Participants' accounts of risk management medicines form a complex picture, where the arguments of personal health promotion and a view that one *has to* take medicines against CVD

risk are combined. The last few quotes display yet another aspect of how participants apply an individual perspective in understanding risk management prescribing; the conclusion that medicine-taking adds to healthiness was based solely on one's own situation and did not extend to the population perspective.

#### *6.4.3 Concluding the subtheme*

Risk management medicines are interpreted as effective against personal CVD risk – they are a way to avoid death and disability from heart attacks and strokes. Some critique was expressed against the strategy of prescribing for prevention, particularly regarding statins. However, scepticism against one type of drugs did not preclude acceptance or perceived necessity of for example blood pressure medicines.

### **6.5 Discussion**

The findings presented under the 'Seeking stability' theme describe how patients evaluate the medicines they are taking and how that informs their understanding of CVD risk management. Below, I discuss the mechanisms around evaluation of medicine-taking in relation to a diagnosis based on risk for future events, and possible challenges to the strategy of prescribing for prevention.

#### *6.5.1 Seeing is believing*

All participants in this study had made the choice to take medicines to do something about their CVD risk. When evaluating the effects of their tablets, participants used several sources of knowledge. Experiences play an important part; it was stressed that the medications have to 'suit you' and many refer to a personal feeling of what is acceptable. In addition, the quantifiable signs that the medicines were effective are a key feature in evaluation.

The visual indication of lowering and stability of the blood pressure was described in terms of providing knowledge that the medicines are effective. This confirms findings in studies of patients' perceptions of blood pressure medicines, where the changes in pressure are a main way to evaluate effect.[185,186] Also participants that expressed initial doubts about various aspects of the risk assessment process (the calculation of an individual's risk for disease, the mechanism of action for medicines, their own need for medicines and also the overall causes for high blood pressure) saw the change as a confirmation of effect. Despite questioning the



reasons underpinning risk management prescribing, once the medicine is ingested and seen to exert an effect on the body, that experience overrides the criticism and medicines become accepted. These empirical findings resonates with two of the themes in the literature review (see chapter 2), that patients' expect medicines to achieve particular effects, and that on-going evaluation of medicines contributes to changeable views on them. In the case of CVD risk management, accessible and practical approaches to depicting the risk condition appear to be strong motivators for treatment.

From seeing that the once high blood pressure or cholesterol has come down due to one or several medicines, participants have concluded that the medicine was effective, thereby justifying its use. This interpretation was also somewhat extended to include wider outcomes; the confirmations of stability were translated as 'everything is fine'. However, the repeated visual indications of stability and control also serve to maintain the image that medications are continuously needed. Confirmation of effect in this way offers patients a way to evaluate and get to know their otherwise intangible condition. As suggested by Nichter and Vuckovic [187] in their outline of anthropological aspects of pharmaceuticals, patients may come to understand a condition by means of the medicine prescribed against it. The interpretation of a controlled biomarker as effect on long-term outcome is also in line with the suggestion by Saukko and colleagues [180] that risk assessment technologies which focus on particular measurable aspects of CVD risk – such as cholesterol or blood pressure – shape patients' understanding of what the risk is and which interventions will be useful to manage it. The visible effects on biomarkers become a way to understand also the CVD risk, and this creates a feed-back loop that supports the need for medicines. It also adds to the picture of CVD risk as being a specific condition rather than a classification according to designated thresholds.

The production and recording of data – blood pressure readings and cholesterol tests – that shows the induced stability appears to support patients' reasoning. As suggested by Berg and Bowker,[188] medical records play a part in showing, but also defining, patients' bodies. In my study, participants readily referred to their own measurements and those done by GPs and nurses as confirmations that the medicines were effective and their state was good. Thus, a type of data that is defined by a biomedical view of the body and closely connected to the principle of cohort approaches in medicine appears to also be embedded and interpreted within patients' daily lives. Following the reasoning by Mol [189] this visualisation of CVD risk in the form of controlled biomarkers offers experiential knowledge of what CVD risk is; it confirms that there was indeed a condition which is now being managed.

Although the medicines contributed to the establishment of an ontology of CVD risk for the low risk patients (who had no experience of cardiovascular ill health), their significant role did not fully make the condition a disease in participants' accounts. For example, indications that the long-term usage of prescribed medicines means getting labelled as sick or that it infringes on people's autonomy or integrity [41] were largely absent in my data. Instead, participants showed how normalised the risk management medicines are by telling me how they discussed them with friends and colleagues. Strategies to avoid medicine-taking [98] were also absent, apart from the alternatives to tablets (diet, exercise and avoiding tobacco) that were mentioned by some participants. The tablets had been incorporated into daily life and I heard many examples of how simple it was to just take them every day. Having to take tablets is seen as either simply a routine thing or as an unfortunate but necessary sign of getting older. In spite of placing CVD risk in a context of dramatic personal illness, the medicines taken to avoid it are, or quickly become, an undramatic part of everyday health work. The interpretation of the CVD risk diagnosis as serious and the subsequent suggestion about treatment as personalised advice (see chapter 5, sections 5.6 and 5.7) might explain this observation.

A major argument in explaining why to use medicines is that the doctor recommended them. The recurring logic referred to by patients is 'my GP would not prescribe the medicine to me if it was not going to be beneficial'. Perhaps this can explain why the medicines were not seen as a negative labelling – they are justified since they are necessary for the treatment of a supposedly serious condition. Interpreting the application of a clinical guidance as a personalised recommendation undercuts a main principle of population-level risk management. Here, as in the case of interpreting the relation between the CVD risk diagnosis and possible outcomes, the denominator used by patients is again their own singular person.

### *6.5.2 Sources of doubt*

In terms of patients' views on CVD risk management as a health care strategy, the conclusions from the interviews divide in two. There was uniform acceptance of using medicines to achieve control over one's blood pressure and thus over one's risk; those medicines do not infringe to any particular extent on daily life and taking them is seen as a small effort for the anticipated gain. Since the risk management medicines were depicted by patients' as a way to promote health, it was feasible even for people that doubted the generalisability of risk assessment data to themselves to come to the conclusion that they should keep taking tablets. However,

participants also expressed criticism against aspects of prescribing for the purpose of risk management.

Here, the apparent difference between anti-hypertensives and statins comes to attention. In the interviews, the value of the former type of medicines was uncontested by participants whereas the latter were to some extent doubted. Regarding statins, suggestions were put forward about financial rather than health-related motives for prescribing, in a way similar to what I found in the analysis of newspaper articles (see section 3.6.4). The changeable environment of advice about health and medicines was seen as confusing; one example being the public debate around statins. Some participants referred to their own experience of GPs seeming to have an agenda of wanting to find conditions to prescribe medicines against, and formulated this as general criticism against extended prescribing. These views stand in contrast to the description of statins as a safe, simple and straightforward way of managing CVD risk and saving lives that was communicated in some of the newspaper articles about them (see chapter 3, section 3.6.)

In the light of patients' desire for confirmation of medicines' effects, the availability of self-measuring devices for blood pressure but not for blood cholesterol might facilitate the building of trust in anti-hypertensives in a way that is not currently possible for statins. Anti-hypertensives were thought to be safe and reliable – their place in CVD risk management was fully accepted by participants in this study, much on the basis of their clearly visible effect on the blood pressure. In contrast to the heavily debated statins, neither the recent questioning of the historically accepted associations between blood pressure and CVD mortality found in the Framingham study [182] nor reminders of the complexity of risk assessment and management [190] have reached the public debate.

In the case of blood pressure the monitors are even owned and thus incorporated into daily life, making it possible for patients to fully engage with the responsibility for risk management. Monitoring creates a context for the daily medicine-taking, by confirming effects and reassuring patients that the daily routine will bring about some change also in the future. Besides perhaps being used as an explanation by the prescribing GP, this message is also abundant in the public domain. As charities strive to increase awareness around the consequences of disease and pharmaceutical companies strive to maximise their markets, public campaigns have planted the idea that medicines against risk promote health and longevity.[61,135] Patients' knowledge and understanding could thus be influenced by the

narrative that depicts taking control over one's cholesterol and blood pressure as favourable, and medicines as the way to do so.

Intervening towards risk by prescribing medicines has traditionally been considered a specific, exceptionalistic approach in prevention strategies – in contrast to broad, universalistic ones that promote health for whole populations. [75,191] (see also chapter 1, section 1.4) What comes across in my interviews is an indication that this might have changed in patients' views. This confirms the finding of the previous chapter; that medicine-taking fits in amongst other efforts to increase or maintain health and is not primarily a demarcation of illness.

## **6.6 Summary**

Participants interpreted the stability gained from medicines as indicative about future outcomes. This resembles the biomedical model where the risk for CVD is represented by a number of isolated associations between biomarkers, behaviours, incidence and mortality. In this sense, participants have adopted a reasoning that is patterned after the campaigns to raise awareness about, and promote interventions towards, CVD.

After this detailed account of the findings in the empirical part of my study, I will now review them together with what I learned from the two literature reviews and consider the overall findings in my research.

## Chapter 7

### Review and discussion of findings

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#### **7.1 Chapter overview: Formulating an answer to the research question**

In this chapter I reflect on the findings in the three studies – the two reviews of scientific and lay literature, and the interview study – and give my account of the research problem that was formulated at the beginning of this thesis. Hence, I will consider how the new knowledge about patients’ views and practices around medicines presented in this thesis can contribute to a better understanding of the complex issue of polypharmacy (see section 1.1) and how my findings contribute to shaping the concept of pharmaceuticalisation (see section 1.3.3).

Over the course of the research, I have addressed different aspects of the research question “What are the influences on patients’ understanding of the use of medicines in cardiovascular risk management?” Contributions from each study are presented below, and combined in a discussion about how patients’ views shape the use of medicines in CVD risk management.

Possible implications of the findings are considered for health care practitioners, policy-makers and scholars working on issues related to pharmaceuticalisation and excessive use of medicines. To relate my findings to the field of polypharmacy, I discuss them in the light of three recent documents on the prescribing and use of medicines; one from a professional organisation, one commissioned by an independent think tank and one reflecting the views of UK health care policy-makers. The documents are the Royal Pharmaceutical Society’s report on Medicine’s optimisation,[24] the King’s Fund report on Polypharmacy and medicines optimisation [1] and the NHS five year forward view developed by NHS England, Public Health England, Monitor, Health Education England, the Care Quality Commission and the NHS Trust Development Authority.[23] This critical review of my findings will consider what incorporating a more comprehensive model of patients’ views of medicines would mean for the efforts to manage polypharmacy.

## 7.2 General influences on patients' expectations of medicines – findings in the literature review

The review and synthesis of literature on patients' expectations of medicines (chapter 2) was a scoping, exploratory analysis at the start of this research project. Its research questions were: "What are the influences on patients' expectations regarding prescribed medicines?" and "What benefits do patients expect from medicines prescribed for long-term prevention of disease?" Descriptions of influences on views, beliefs and expectations were collected from empirical studies of medicine-taking for a range of conditions. Thematic synthesis produced four themes showing different types of influences on patients' expectations on medicines. The themes are outlined in figure 7.a, together with the major findings that informed the subsequent parts of my research.

Themes and findings of importance to the overall research question	
A need to achieve a specific outcome	<p>Naming of specific targets with treatment</p> <p>Confirmation of effect on targets</p> <p>Wishes for high and guaranteed benefit from risk management medicines</p>
Experiences and evaluation develop over time	<p>Own and vicarious experiences are used</p> <p>Medical and social sources of information</p>
Negative values – dependency, criticism and social stigma	<p>Certain medicines have negative associations</p> <p>Number of medicines might be too high</p>
A personalized meaning of medicines; their necessity and usefulness	<p>The view on medicines is related to one's personal understanding of health and illness</p> <p>Medicines have different roles in peoples' lives, e.g. helping or hindering normality</p>

Figure 7.a Summary of the findings in the review and synthesis of literature on patients' expectations.

This analysis provided me with an overview of the mechanisms that influence patients' expectations. In terms of informing me about the particular field of CVD risk management prescribing, a number of aspects were identified. One was the significance of specified targets for treatment. In symptomatic illness, those targets reflected the symptoms. In the case of risk management, patients had likewise specific expectations that the medicines would produce

certain effects. There were indications that patients expect more benefit from such medications than is clinically possible, for example larger risk reduction and longer predicted survival time. Another prominent gap between the biomedical and patient-based understanding was indicated by how patients seem to expect guarantees of beneficial effects from preventive medications such as anti-hypertensives and statins.

From the review, I could also conclude that experiences play a large role in patients' short- and long term evaluation of medicines. Perceived effects of medicines are balanced with illness symptoms, for example in cycles of testing a medicine's effect versus illness symptoms. Vicarious experiences and professional as well as lay advice also go into the evaluation process. This raised the question about which mechanisms are at play in the sense-making around interventions targeting asymptomatic CVD risk, where no symptoms or improvement are tangible but an abundance of information is available: positive and negative accounts are disseminated by health care professionals, the media and perhaps also shared in discussions among peers.

The theme describing personalised meaning of medicines' usefulness and necessity highlighted how patients using medicines for the same condition can hold different and even opposing expectations of the function of the medication in their lives. It indicated that the position of a medicine within a patients' understanding of health and illness is strongly influential on what the medicine is expected to do. If the understanding of CVD risk management medicines is similarly individualised, that highlights a possible tension regarding the idea behind large-scale prevention strategies where many people need to take treatment for the average benefits to be delivered.

This first study confirmed the possible diversity of views of medicines and their use that is reflected in the sociological literature (see chapter 2, section 2.2 for examples), since my overall finding was that patients' views on medicines and the usage of them are indeed more complex than accounted for in a biomedical description of health promotion and risk management. It highlighted patients' conceptualisation of preventive benefit from medicines as particularly different from that which is offered on a biomedical basis. Thus, it strengthened the focus for my research towards exploring patients' understanding of the concept of CVD risk as a way to investigate the consequences of extended risk management prescribing.

### 7.3 Societal influences on people's concepts of CVD risk management – findings in the review of newspaper articles

The review and thematic analysis of descriptions of CVD risk and risk management in UK newspaper articles (chapter 3) focused on how a message about new guidelines for risk assessment and prescribing of statins transferred from the professional and policy perspective into a lay context in print media. The research question in this study was “What representations of CVD risk, and the benefits and harms of statins in managing that risk, are communicated by UK newspapers?” Four themes were identified; see figure 7.b.

Themes and findings of importance to the overall research question	
CVD risk is identifiable and measurable	CVD risk presented as a combination of individual, specific risk factors Risk assessment is not questioned
Statins save lives – but they also cause problems	Statins are protective and ‘cut’ the risk for disease Benefits are presented as summary measures on the population level; harms as individual stories about debilitating side effects
Making an informed choice	Readers were encouraged to consider their own risk and make a personal decision about whether to use medication Some newspapers took on the role of guiding people to a decision
CVD risk management is a medical issue	References to social determinants of health, such as the link between poverty and CVD, were largely absent in the articles Despite criticism against medicalisation of unhealthy lifestyles, suggestions about approaches to improve the situation did not go beyond saying that individuals need to change their habits

Figure 7.b Summary of the findings in the analysis of newspaper articles about statins in CVD risk management.

One influence on patients’ understanding of medicines for CVD risk management was indicated in the newspapers’ portrayal of the risk itself. Age, sex and lifestyle factors were given as causes of CVD risk and some articles offered examples of how combinations of these make people eligible for treatment under the new guideline. The naming of specific causes was accompanied by statements that encouraged people to address their own situation and decrease



the risk by living healthily – possibly with the help of medicines. Newspapers presented CVD risk as a distinct condition that can be identified and controlled.

Alongside the rather contained image of CVD risk, the newspapers presented a more diverse account of the medicines prescribed to control it. The message from NICE about how many lives would be saved by increased prescribing and use of statins was complemented by accounts of various negative effects from the medicines, illustrated by personal stories and observational studies. The presentation of evidence produced in randomised clinical trials side by side with experience-based and observational data broadens the image of effects from statins and provides people with examples of when the decision to use them has had negative consequences. It may also indicate to readers that personal experience plays an important part in decisions about medicines. Thus, the implied control over risk was complemented with aspects of uncertainty originating from medicines.

While reiterating the message from policymakers that statins are effective, safe and cheap, the reporting in newspapers also reflected the complex balancing of medical information, experiences and personal views in making decisions for individuals. Critical accounts of the quality of data underpinning the new guideline and possible influence from private interests added elements of uncertainty to the image of CVD risk management with statins. However, in response to the difficult decision about whether to use statins or not, the newspapers recommended that readers see their GP to get personalised advice on what is right for them. This reframes the complex issue of CVD risk management in a seemingly simpler context of professional expertise and presents it as a predominantly medical issue. Adding to the medical framing was the fact that other possible discourses about cardiovascular health were absent from the descriptions. Articles focused the stories on whether or not to take tablets in response to a diagnosis instead of discussing for example social determinants of health, the availability of food, alcohol and tobacco or the link between poverty and CVD.

In summary, I saw a variation in the newspapers' presentation of different aspects of CVD risk management. While the risk for disease was portrayed as an established condition, the medicines used in its management were presented in a context of uncertainty regarding both positive and negative effects. The newspapers place the individual person at the centre of decisions about statins, and GPs are appointed as the experts to help negotiate risk, benefit and harm.

## 7.4 Individual understandings of using CVD risk management medicines – findings in the empirical study

The empirical part of this project was my opportunity to directly address patients' understandings of CVD risk management. My research question was "How do patients conceptualise CVD risk management with medicines?" The interviews explored each participant's experiences and views, and also made it possible to test emerging conclusions from the two literature studies. Thematic analysis produced the two themes described in chapters 5 and 6, namely how patients perceive being at risk for CVD and how they understand medicines as a way to manage that risk. The themes are summarised in figure 7.c.

Themes and findings of importance to the overall research question	
Being at risk	A CVD risk diagnosis is pictured in terms of its ultimate consequences
	Knowing about the risk encourages patients to take action to lower it
	A GP's suggestion about risk management treatment is interpreted as personally adapted advice
Seeking stability	Effect on biomarkers confirms that the medicine was needed and is beneficial
	Controlled biomarkers are interpreted as controlled risk

Figure 7.c Summary of the findings in the interview study.

My starting point for this thesis was to question what makes people accept and take CVD risk management medicines despite the low and indiscernible benefit. In the empirical part of the project I set out to investigate what might influence patients' understanding of the benefits from such medicines. I can now put together some factors that seem important in explaining it.

An individualised interpretation, shaped by personal or family experience and advice from a health care professional, is the foremost mechanism that explains patients' reasoning and actions. Information indicating both negative (the consequences of having high blood pressure, the risk for side effects) and positive (benefit from CVD risk management medicines) events is interpreted not as 'one chance in a large number' but as being about a specific person. In short, it seems like medical information made available to people gets applied to oneself.

The CVD risk conditions of high blood pressure and high blood cholesterol were predominantly understood in a medical context rather than a social one, and portrayed in terms of their potential to cause heart attacks and strokes. With the individually based reasoning just mentioned, participants thus saw the diagnosis as a personal indication of imminent, severe illness. Since the information about the risk was given to people by their GP, it was deemed to be valid and valuable for them as individuals. In a similar way, the medicines prescribed to manage CVD risk factors were seen as beneficial for the individual. Participants referred to visual clues of effects that were available to them – the lowered and stable blood pressure and cholesterol showed that the medicines worked.

The conclusion that the individual person is at the centre of patients' reasoning is also supported by how it can be traced in their negative notions about CVD risk management. One example of this is the question of whether the otherwise trusted scientific base for decisions to intervene to contain risk were true 'for me'. In other words, some participants told me they trusted the science and the benefit of medicines in principle, but had their doubts about applying it directly to themselves. Strategies used to overcome that doubt were either seeking support in the decision from one's doctor, or trusting one's own experience from trying and evaluating the medication for discernible immediate effects.

Regular monitoring of biomarkers offers a connection between medicine-taking and medicines' effects, and what is seen is interpreted by patients as a sign of benefit from the medicines. The stabilised blood pressure and cholesterol were understood as straightforward indicators of a lower risk for future events. Thus, patients used the visualised effects as a context that linked their daily tablets with future health and also confirmed that the doctor was right in suggesting that treatment was needed. Whilst being consistent with the underlying principle for risk management prescribing, patients' perception of the situation entails two types of exaggeration of the association between biomarkers and outcomes: they manifest themselves as an overestimation of the level of preventive effect, and in the assumption that both the CVD risk and the benefit from medicines are directly applicable to oneself.

Taken together, patients' conceptualisation of medicines for CVD risk management seems to involve a personal interpretation of the risk and the benefits from attempts to contain it. The actions prompted originate from a medical view on health and illness, since the risk is mediated by health care professionals. Feedback in terms of effect on biomarkers is used as a

confirmation of the personal aspect of risk and benefit, and also keeps the reasoning in a medical context.

## 7.5 Patients' understanding of medicines in CVD risk management

When the literature reviews and empirical work are considered together and in relation to the research question, three themes come across as present throughout the findings. These are presented (see table 7.1) and discussed below, showing my suggestions regarding the central influences on patients' understanding of medicines in CVD risk management.

Table 7.1 Key findings in the research, and the overall themes in the study

<b>General influences on patients' expectations</b>	<b>Newspapers' representation of CVD risk management</b>	<b>Patients' conceptualisation of medicines in CVD risk management</b>	<b>Overall themes in the study</b>
Patients expect guaranteed outcomes and more benefit than clinically available	Risk can be identified, measured and controlled	A diagnosed CVD risk needs to be treated with medicines	A simplified representation of CVD risk and risk management
Experiences inform an ongoing evaluation of the utility of medicines	Medicines have both positive and negative effects, that need to be balanced by the individual	Individualised interpretation of CVD risk and benefit from medicines	A desire for defined and identifiable effects from medicines
The role of medicines is shaped by personal beliefs	Individuals should make their own, informed decision about the need for medicines	Visual feedback confirms the individual interpretation of CVD risk and benefit from medicines	A responsible patient expecting personal benefit from medicines

### 7.5.1 A simplified representation of CVD risk and risk management

The 'patients' perspective' image of CVD risk that emerges from the findings in this project is one of a defined condition that can be measured by medical instruments and controlled with medications. Although patients may have unrealistic expectations on the level of risk reduction available, their approach to the condition is in fact close to the one presented in information

about CVD prevention published by for example the NHS and NICE. These emphasise risk factors such as blood pressure, cholesterol levels, age and lifestyle and also provide summary figures of how many people die from cardiovascular events every year. Patients have internalised the biomedical understanding of an association between biomarkers and risk level, and that getting older will lead to a need for medicines. The fact that a risk is diagnosed seems to indicate that it is valid – GPs are trusted representatives of a likewise trusted medical science – and once it is known about, it cannot be ignored. Here, my findings indicate that CVD risk might be perceived as a more serious threat to health and wellbeing than other diagnoses that lead to preventive medicines. Other studies on patients' decisions about whether to engage with long-term prevention (of type 2 diabetes and osteoporosis) report more varied reactions to suggestions about treatment, including doubt regarding medicines' possible beneficial effects [104,107,108] and the need for experiencing symptoms before the diagnosis is seen as a reason to take action.[105] Notions that aging bodies will suffer from increasingly frail hearts and blood vessels and thus are quite likely to die from a heart-related condition – or even that everybody will eventually die from something – are not present. Neither are acknowledgements that risk factors have a weak predictive value for CVD-related mortality.[192]

Further explanation for patients' views on CVD risk comes from the importance of experiences in the evaluation of illness and medicines. When a diagnosed condition is asymptomatic, such as elevated blood pressure or cholesterol, patients draw on other types of experiences: cases of illness in the family or among friends become examples of what might happen if the risk is not contained. The result of the risk assessment, which isolates a few features of the individual's situation and predicts the risk for a certain type of events, gets interpreted in terms of impact in a context that encompasses many more aspects of life. In their response to a CVD risk diagnosis, patients apply a risk score which represents an average measure in a population to themselves.

The simplified representation of CVD risk and its management indicates that the meaning and character of preventive prescribing has changed since the strategy was adopted. When large-scale intervention was introduced as a method to prevent CVD, the discourse differentiated between individual and population approaches.[76,192] The former, consisting of prescribing medicines or devising lifestyle changes for people at high risk, was seen as specific but requiring the motivated effort of individuals and clinicians. The latter, aiming to lower incidence of disease by decreasing exposure in a whole population, requires a compliant population that accepts changes such as lower salt-content in food or restrictions on tobacco

smoking. One conclusion from the current character of CVD risk and risk management that I have encountered in this study is that the concepts of individual and population strategies are starting to overlap. Drawing mainly on the findings in the interviews and the analysis of newspaper articles I find that risk for CVD is normalised as a common condition, but also interpreted as a disease that warrants intervention. Lifestyle changes are everybody's responsibility, not just encouraged for those at high risk. Even a slightly elevated risk is now indication for prescribing [73,182], and the argument of 'might as well' is used as a reason to take medicines.

#### *7.5.2 A need for defined and identifiable effects from medicines*

The importance of tangible signs of medicines' effects has been clear in all three studies, and in patients' understanding of CVD risk management this is provided by monitoring of biomarkers. This reflects findings in other studies of medicine-taking in asymptomatic risk management, where numerical representations are reported by patients to be helpful when evaluating their medicines.[105,108,193] Medicines seen as doing a specific job in lowering the blood pressure and cholesterol is a recurrent interpretation of the phenomenon of risk management. This view of preventive medications resonates with the biomedical description of CVD risk that was offered by newspapers and also dominated in patients' accounts. In short, the medicines are seen as tools to alleviate the risk. Contributing to the expectations of this defined effect from medicines might be the fact that the relation actually emerged the other way around. As shown in critical examinations of pharmaceutical drug development and marketing [61,135], the targeting of risk factors such as blood pressure and cholesterol was initiated only after suitable pharmaceutical compounds that controlled them were identified. Therefore, the available knowledge about CVD risk is entwined with claims about how it is affected by medicines.

As in the case of patients' interpretation of CVD risk, experiences also influence their understanding of medicines prescribed to manage it. Accessible, visual confirmations that one has achieved some change regarding the factors that signify the risk (blood pressure and cholesterol measurements) offer confirmations that the values were actually high – since they are now visibly lower. The emphasis on seeing the biomarkers come down when taking tablets suggests that once treatment has started, the measurements indicate that the action taken was worthwhile and beneficial. Perhaps informed by the popular imagery of CVD risk as closely

connected to biomarkers, the immediate and sustained effect is interpreted as a causal relation that also suggests an effect on CVD morbidity and mortality.

Experiences of side effects are also influential on how medicines are understood in CVD risk management, and the review of literature on expectations identified it as an area where patients' views might differ significantly from a biomedical description. My findings indicate that the negotiation between sources of knowledge regarding side effects is more complex than the straightforward interpretation of medicines' effects on biomarkers. The newspaper articles presented harms and benefits from statins as opposed to each other, indicating that people gave up the tablets completely due to side effects. However, some of their critique towards extended prescribing of statins focused on the inadequate reporting of side effects in the trials that supported the guideline, perhaps suggesting that the correct way to know about statins' effects is to feel for oneself. The interview participants indeed used both negative and positive experienced effects as a way to evaluate prescribed medicines, and balanced them against their general feeling of wellbeing and the perceived severity of the diagnosed CVD risk. This way of including experiences appears to be a recurring finding in qualitative research into long-term use of medicines, and is reported as influential on decisions about antidepressants,[102] medicines prescribed to manage CVD risk,[194] osteoporosis,[104] and type 2 diabetes.[105]

These findings regarding how effects from medicines are interpreted indicate that patients devise a context of experienced and visualised results into which the daily taking of medicines for an asymptomatic condition is fitted. Since biomarkers can be easily assessed and visualised, they become the way that patients understand risk management medicines. The absence (from patients' accounts as well as the newspaper reports) of the concept of risk reduction or other acknowledgements of a less-than-direct relation between biomarkers and future outcome suggests that patients do not necessarily discriminate between immediate and future effects from medicines. Thereby, the accessible signs of controlled blood pressure and cholesterol values shape patients' understanding of the principle of risk management – medicines are seen as contributing to healthiness.

Patients' prioritising of stability as a sign of successful treatment of the asymptomatic CVD risk is not an obvious choice. Alternative indicators could perhaps be reaching the lowest possible blood pressure or cholesterol, striving to use a low number of tablets per day, finding a non-pharmacological way to intervene, or aiming for as little change to one's daily routines as possible. The choice of stability might indicate an influence from pharmaceutical marketing

on patients' perception of value from medicines; it builds on the narrative that health conditions are medical problems that can be solved with medicines [56] and that medications offer the transition from a state associated with disease and uncertainty towards normality and control over one's life and health.[135] It could also reflect the way that health services are set up to treat people 'to evidence based targets' for biomarkers. When no further gain is implied from getting it lower, health care professionals might stop actively encouraging patients to take medicines, and this could be seen as an indication that health is restored.

### *7.5.3 The responsible patient expecting personal benefit from medicines*

Throughout the investigation of influences on patients' understanding of CVD risk and its management, it has been clear that people interpret information, conditions and short and long-term effects from medicines with a perspective that puts themselves at centre. As shown in the two previous sections, the individual person is the denominator for both CVD risks and benefits from medicines. This finding is perhaps not surprising – current public health has been characterised as highly individualistic [195] – but it has implications for the effects of CVD risk management policies for prescribing and practice.

Prevention prescribing focuses on individuals by assessing risk factors that are closely linked to both the social person (lifestyle choices) and the physical body (biomarkers). The messages communicated in NICE's press release about the updated lipid modification guideline [130] were directed to individuals, and used an argument around lifestyle habits that people should adopt – one of them being the use of medicines to keep one's cholesterol under control. CVD risk management is communicated using a language that appoints actions by individuals as the way to achieve the population-level targets.

This imagery of CVD risk management medicines seems to also be the one that patients are using, albeit while attributing the knowledge of what is the right thing to do to their particular doctor instead of to a generalised body of medical evidence. Objective, scientific knowledge is hailed as superior to people's shared experience or industry's objectives, but trusted the most when it is delivered in a subjective form; seen as personal advice from a particular GP. Findings in my interview study indicate that the possible uncertainty about medicines' benefit that was depicted in the newspaper analysis is resolved with trust in the personally adapted advice from a doctor. Other literature on patients' understanding of medications prescribed to prevent future ill health, both in CVD risk management and in prevention of fractures in osteoporosis or



complications arising from diabetes, also suggest that the role of the GP (or other well-known physician) is important for patients' decisions about using medicines.[107,109,194]

#### *7.5.4 Remaining gaps in the description of patients' understanding of medicines in CVD risk management*

Although findings in the studies largely add to each other, there were also some areas where gaps remain. One of them relates to the role of social determinants of health as a risk factor for disease and a driving force behind prescribing of medicines. As mentioned in chapter 3, the link between for example poverty and CVD was largely absent in the newspapers' reports about CVD and risk management. Lifestyle was mentioned as contributing to the risk for disease, but structural factors were neither addressed as causes nor interventions for improvement. In contrast, the significance of poverty and education on health in general was alluded to by some interview participants, saying they themselves were able make good decisions and could afford to eat well but others might not be able to.

The gap between social and biomedical understandings of CVD and its prevention is present also in the criticism against increased prescribing as a way to manage risk. Cohort strategies, influence from the pharmaceutical industry and 'too much prescribing' in general were addressed by interview participants and in many of the newspaper articles. However, the discussion remained linked to medical matters (such as individuals' need for treatment) rather than being connected with social factors (such as people's ability and options to look after their health).

An observation that might challenge the dominance of the biomedical view in patients' understanding of CVD risk management with medicines relates to the prominence of individual interpretation of information about health and disease. As shown above, patients' application of evidence presented by a prescriber to themselves supports the increased use of medicines. However, the same desire for personalised advice was the basis for some interview participants' criticism and avoidance of medicines. One example is the interpretation of CVD risk assessment as over-generalised procedures with little relevance "for me". Some participants also expressed a view of GPs as limited to acting within a certain dogma or policy instead of adopting a holistic view of their patient's health. These participants were happy to take medicines for conditions where they had some experience of symptoms or consequences (personal or vicarious), but were critical of prescribing for reasons other than tangible health problems.

The scoping interviews with GPs at the start of this study (see appendix A1) indicated their trust in the guidelines for CVD risk management. Although they had different views on how to motivate patients to engage with treatment, they shared the opinion that the guidelines reflect best practice and should be followed for the benefit of both singular patients and whole populations. Thus, the personally adapted guidance from a GP – which contributed strongly to the interview participants’ decision to accept medicines and also was put forwards by the newspapers – did not correspond to how the GPs described their practice. The initial scoping interviews also indicated that organisation, the availability of guidelines, drug prices and GPs’ personal approaches to prescribing for risk management influenced their advice to patients.

## **7.6 Situating the new knowledge – relations to CVD prevention policy and practice, polypharmacy and pharmaceuticalisation**

In this section, I summarise the new knowledge that arises from my study and suggest what it might mean in relation to the areas that form the background for the research. Since I used CVD risk management prescribing as the setting in which I examined patients’ views on medicines, the major findings in this study relate to this particular way of prescribing and using medicines. However, the research was undertaken with an aim to contribute new knowledge about polypharmacy, and thus I will suggest how it adds aspects to the current discourse of multiple medicines prescribing and use. Lastly, I will also return to the theoretical background of my study and comment on what the findings might contribute in terms of the evolving concept of pharmaceuticalisation.

To guide this examination of what my research has contributed, I will relate the findings to three current reports which address the same area as my research; polypharmacy, health promotion and the use of medicines in the UK. The ‘NHS five year forward view’ from 2014 stresses the importance of health promotion for the future of the NHS and the country,[23] highlighting prevention as a shared responsibility between communities and the health care system. The King’s Fund report Polypharmacy and medicines optimisation – making it safe and sound [1] was published in 2013 with the aim of giving an overview of the knowledge about polypharmacy and also to suggest some solutions to problematic issues. Published in the same year, the Royal Pharmaceutical Society’s report Medicine’s optimisation: Helping patients to make the most of medicines [24] had the objective to get practitioners and patients to work closer together to improve the use of medicines. In table 7.2, I summarise the key

points from the reports that are applicable to the use of medicines in disease prevention and how my study supports, challenges or extends them.

Table 7.2 Implications of my findings for current efforts in the field of polypharmacy, CVD prevention and prescribing.

Report	Findings in this study	Implications of my findings
<b>NHS five year forward view</b>		
<ul style="list-style-type: none"> <li>- Patient and community engagement is central to effective prevention of disease, as patterns of ill health are linked to geographical regions and conserved through generations</li> <li>- National action on smoking and consumption of alcohol, junk food and sugar will be reinforced by the NHS</li> <li>- Failure to increase engagement with prevention of disease will have implications for health inequalities and life expectancy, and lead to unnecessary health care spending</li> </ul>	<p>If health effects of aging or lifestyle are presented as diagnoses, people will see it as their responsibility to take medicines in order to maintain health</p> <p>Visible stabilisation of biomarkers is a key part of patients' understanding of how their health is improved when they take medicines</p>	<p>Primary care gets a reactive role in relation to other parts of society, where consumption habits continue to cause the ill health that is mentioned as targets for preventive efforts</p> <p>Perhaps health improvement of for example stopping smoking is less valued by patients, since it does not give as clear representation of change as medicines do</p>
<b>Polypharmacy and medicines optimisation – making it safe and sound</b>		
<ul style="list-style-type: none"> <li>- Polypharmacy is not about the number of medications but about their management; it can be appropriate in some cases while problematic in others</li> <li>- Clinicians should avoid 'prescribing cascades' and ensure clinical benefit from all prescribed medicines</li> <li>- Patients' views on medicine-taking are important but potentially different from prescribers' views*, and a compromise about appropriateness might be necessary</li> </ul>	<p>Taking a few medicines can be interpreted by patients as necessary due to aging</p> <p>Risk reduction (the evidence /information from GP and the controlled biomarkers) is interpreted by patients as personally adapted advice with considerable applicability for themselves</p>	<p>The notion of appropriateness of medicines gets new dimensions by patients' feeling of responsibility towards a diagnosed risk for CVD – with the strong trust in personal advice from a GP, even a small potential benefit is perceived as need for treatment</p> <p><i>(table continues overleaf)</i></p>

<b>Medicine's optimisation: Helping patients to make the most of medicines</b>		
<ul style="list-style-type: none"> <li>- Medicines optimisation means prescribing according to evidence and ensuring that medicines are taken safely and correctly, for best clinical outcome and patient experience</li> <li>- Patient-centred, individualised care, including reflection on medicines optimisation, should be part of routine practice</li> <li>- Examples of patients' views focus on technical and practical aspects (dosage times, safe packaging), and optimal use entails making patients knowledgeable, engaged and confident about taking medicines</li> </ul>	<p>Patients' optimal outcomes from medicines are when you "feel ok" and see clear effects (for example stabilisation of biomarkers)</p> <p>Optimal use in daily life might not correspond to medical instructions – for example, some testing of effects can be necessary to establish that the medicines "do their job"</p>	<p>Truly patient-centred care might need to be clearer about the evidence behind medicines' effects at low levels of risk</p> <p>Advice to ascertain that patients are taking medicines as instructed might need to allow for a period of patients' testing of effects</p>

\*However, the report does not elaborate on what they might be.

### *7.6.1 Implications for CVD prevention policy and practice*

In relation to the current policy for CVD prevention, which is framed by the NHS health checks, [65] my findings highlight some aspects that have implications for the impact of this approach to promoting health and preventing disease.

The most notable finding is the emphasis on personalised advice from one's GP, and the trust placed in a diagnosis of CVD risk when it is mentioned by a health care practitioner that is seen as providing specific advice "for me". Although the notion of patient-centred care and joint decisions about medicines is present throughout the guidance about CVD prevention – and emphasised in for example the NICE patient decision aid about statins [165] – the rationale for a population approach is to treat cohorts to reap benefits on the large scale. Services are set up according to this, with short appointments for checking biomarkers and issuing prescriptions. The finding in my study – that patients view their GP as a personal interpreter and mediator between a body of medical science and their own life and wellbeing – thus demands a different role for GPs to be trained for and take on in their practice.

The emphasis on patient-centred care also gets a new dimension by the finding in my study that patients overestimate the individual threat to health from a diagnosed CVD risk and also the individual benefit gained from medicines. Considering the important role of trust in one's doctor, CVD risk management could present GPs with a challenge if they are to offer patients a truly informed choice. Being clear about the level of risk reduction that medicines actually offer might threaten the perception of individual applicability of both the risk and the protection from medicines, and thereby undermine patients' trust in the concept of CVD prevention.

### *7.6.2 Implications for the UK discourse on polypharmacy*

Two of the reports (from the King's Fund and the Royal Pharmaceutical Society) have a strong biomedical focus on health, disease and medicines, where patients' views are pictured as centred on the practical aspects of medicines use. Notably, the report from the King's Fund points to the limited knowledge about patients' views of medicine-taking, and calls for it to be determined. This indicates that my findings can add valuable knowledge, by proposing an outline of patients' reasoning around the need for, and effects of, medicines. For example, practicalities such as opening packages or understanding instructions did not come across as a concern for participants in this study, whereas getting diagnosed with high blood pressure represented something that had an impact on many patients' lives. Perhaps the efforts to reach promote optimal use of medicines also need to consider the consequences of suggesting that medicines could be needed?

### *7.6.3 Implications for scholars researching the use of medicines*

The link between lifestyle, health and disease that is present throughout policy documents on CVD prevention also has potential connections to the concept of pharmaceuticalisation. When patients see medicines both as a way to manage the diagnosed risk and as a proactive step towards health, the medical framing of obesity, smoking and drinking could lead to an ever-increasing perceived need for medicines. If taking medicines for CVD prevention is not seen as necessary 'labelling' people, and the straightforward signs of effects from tablets are valuable in patients' sense-making regarding the concept of risk, pharmaceutical intervention might outweigh other types of risk reduction (e.g. smoking cessation) that does not produce equally clear results.

Revisiting the theoretical background for this study, my findings resonate with several of the dimensions of pharmaceuticalisation suggested by Williams and colleagues (see section

1.3.3).[56] The conclusion in this study that medicines are presented to, and perceived by, patients to fully solve the issue of CVD risk corresponds to the phenomenon described as *Selling sickness*. Also the aspect called *Mediation* can be recognised in my findings; the newspaper presentations of extended prescribing of statins was dominated by personal accounts while still framing CVD in medical context and offering space to people directly promoting extended use of pharmaceuticals. The animated and lengthy debate in the daily press of a medical issue, where the discussion about prescribing has moved into an arena for issues spanning daily life as well as politics and business, supports the idea of a conceptual shift from medicalisation to pharmaceuticalisation as an explanatory theory for the power relations surrounding the use of medicines. While medicalisation described a situation of diminishing people's own abilities to deal with health matters and instead placing such things under professional control, pharmaceuticalisation places that responsibility back with people. Potential patients are given the task to monitor their health and make choices about it – albeit in a medical framing.

One major finding in this study – that patients' understanding of CVD risk management prescribing fosters a sense of responsibility which leads them to incorporate medicines into their lives as a way to stay or get healthy – also indicates that medical and social arguments are re-negotiated in the field of medicines use. People (newspaper readers as well as those that participated in my interview study) are active both as patients and as consumers when engaging with medicines for the purpose of improving their own lives, as described in the dimensions *Patients, consumers and the life world* and *From treatment to enhancement?*.

A possible addition to the concept of pharmaceuticalisation is the role of doctors (here, an NHS GP) in establishing trust in the medicines that are suggested and promoted by the surrounding social world. This position of mediating between a vast body of medical knowledge and a singular individual, and possibly also as a gatekeeper between a patient and a tool for increased healthiness, could be a basis for exploring the place of medical professionals in the use of medicines in a context influenced by private interests.

## 7.7 Summary

In this chapter, findings from my two reviews of literature and the interview study have come together in an account of CVD risk management that shows how patients understand the

diagnosis of risk factors and the medicines prescribed to prevent disease. A biomedical description of health and medicines is present in patients' reasoning, for example informing how CVD risk is pictured. However, the biomedical model is interpreted with an individual perspective that forms the basis for patients' decisions about medicines.

To situate my findings in relation to the background for the study, I have discussed them in relation to recent three reports about different aspects of prescribing, polypharmacy and health promotion. The comparison suggests additions to the concept of appropriateness in prescribing, and points to the possible effects of considering a patients' perspective based on experiences when prescribing for prevention in primary care. In addition, I have reviewed the suggested framework of pharmaceuticalisation in the light of CVD prevention.

In the next and final chapter, I shall review the trustworthiness of my research using the criteria outlined in chapter 4 (see section 4.7 and table 4.4), and ultimately consider how this study has created knowledge that adds to the characterisation of the complex phenomenon of polypharmacy.

## Chapter 8

### Conclusions: New perspectives on polypharmacy

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#### **8.1 Chapter overview: Summary and critical review of findings**

In this thesis, I have explored patients' understanding of medicines in CVD risk management. This particular way of using medicines was used as a topical and rich example of prescribing, with the aim of learning about some of the mechanisms that influence polypharmacy. Cardiovascular risk management in primary care is supported by a growing (but challenged) body of evidence implemented via clinical guidance that makes an increasing number of people eligible for medications. At the same time, increased prescribing is criticised for creating problems on both an individual and a systems level.

In this final chapter, I consider what patients' understanding of CVD prevention with medicines might add to the knowledge about the complex issue of polypharmacy. To demonstrate the trustworthiness of my findings, I critically review them in relation to my study design and methods. Finally, I conclude with what this study adds, and give some suggestions of what could be addressed in further research.

#### **8.2 New perspectives on polypharmacy**

This study adds some knowledge about the biomedical view of polypharmacy, and also some things that relate to other views on health and medicines.

The two reviews of scientific and lay literature showed that patients use experiences and personal understanding as well as medical information when making sense of the need for medicines. That informed my interview study, in which I sought to clarify how patients balance CVD risk with possible benefit and harm from medications when making decisions about their own medicine-taking. What I found was an acceptance of medications built on reasoning around an individualised interpretation of CVD risk, responsibility for engaging with health matters and trust in health care professionals. My study indicates that the main influences on patients' understanding of medicines in CVD risk management are i) the acceptance of a biomedical view of what CVD risk is and how it can be managed, ii) the use of tangible signs



in evaluation of medicines, and iii) the application of an individual perspective in making sense of a strategy that is designed for populations, leading to overestimation of benefit.

### *8.2.1 Appropriateness of medicines*

My findings indicate that patients accept a biomedical model of health and illness, where disease can be measured with instruments and controlled with medications. Moreover, patients seem to take the medical involvement *per se* as an indicator of need for intervention. The absence of symptoms appears to be of less importance – an expert’s biomedical description is readily adopted and interpreted as a need for medicines. Patients referred to the body of medical science, represented by their own GP, as the guarantor of the need being valid. In relation to understanding polypharmacy as an effect of medical progress, these findings point to a view that aspects of life which have in some way been characterised as related to disease will eventually become reasons for needing medicines.

Strategies originating from the medical community to counteract problematic polypharmacy often mention doctors’ responsibility to listen to patients’ choice about whether to use medicines or not. However, I found that when a diagnosis is made and treatment suggested by the trusted doctor, patients see it as obvious that medication is necessary and will be beneficial. This challenges the principle of informed decision making and undercuts the component of rational prescribing that stresses that treatment shall be *offered* or *suggested* to patients; once a CVD risk diagnosis is mentioned by a doctor it seems to be ‘too late’ since patients interpret it as a direct prediction of disease.

The current biomedical view on polypharmacy uses the achievement of clinical benefit as an indicator of appropriateness of prescribed medicines. Patients’ understanding of positive effects from their tablets adds dimensions to that understanding of benefit. What I found was that the visualised immediate effects from medicines become interpreted as signs of improvement of both present and future health. In situations where the treatment provides a visible effect (such as anti-hypertensives on blood pressure and statins on cholesterol), medicines therefore seem to have the capacity to ‘prove their own necessity’. This view of benefit, described by patients in my study, corresponds to both GPs’ targeting of biomarkers and the narrative in public campaigns related to cardiovascular health.

### *8.2.2 Medicines' role in health and everyday life*

Some findings from my study relate to areas that fall outside the biomedical discourse on polypharmacy, and thus point to possible new dimensions of the phenomenon.

An aspect of patients' understanding of medicines that came through in this study was the notion of medicines being not only the necessary response to a diagnosis but also a way to stay healthy in a wider sense. The 'risk management patient' is not using medicines because of illness, but in an effort to maintain and promote health. This suggests a connection to the idea of medicines as enhancement, which was previously focused on lifestyle aspects such as appearance and sexual performance. Now, also one's blood pressure seems to be a possible area for self-improvement. As long as medicines are communicated as a way to stay healthy, and prescribers continue to be a trusted source of information, they may continue to be accepted. From this perspective, polypharmacy is to some extent an issue of personal inclination; if the patient perceives and trusts the accuracy of a need for medicines, the number of tablets may be less important.

Faced with the asymptomatic diagnosis of 'being at risk for CVD', patients complement the biomedical view with a personal logic of the benefit from medicines. Here, experiences are a valuable source of knowledge about medicines. In line with this reasoning, tangible signs of medicines' effects hold an important position. My findings regarding how effects from medicines are interpreted indicate that patients devise a context of experienced and visualised results. This context is used in personal sense-making about the medicines, which in turn can support further use.

## **8.3 Critical review**

The collection and handling of research data is a process of selection,[94] and all choices of techniques – from sampling and recruitment of research participants to presentation of the findings – have implications for what knowledge the study will generate and display. Therefore, it is necessary to assess the process as a whole when looking at the usefulness of findings. In this section, I discuss the strengths and limitations of my study and how they influence the usefulness of the findings. This critical review starts with revisiting the limitations of the two literature reviews that informed my empirical study. Then I will apply the criteria

for establishing trustworthiness of my interview study and the knowledge it has created, as outlined in chapter 4, section 4.7.

### *8.3.1. Limitations of the literature reviews*

The review of scientific literature on patients' expectations was limited in terms of the databases searched, and also for being carried out mainly by only one person. However, as it was only a starting point for my research and the findings in the review have been confirmed during the course of the project, the consequences of this limitation does not appear to be so significant.

With regards to the influence of my strategies for searching, including and analysing articles on my findings in the review of how CVD risk and risk management are represented in UK newspapers, I suggest two potential limitations which are presented below.

The first limitation is that my analysis does not allow for assessing the importance of newspapers as a source of information about one's own CVD risk. Focusing the searching and reading of newspaper articles on different types of publications, aimed at particular groups of people, might have allowed for checking whether segments of the population were reached by news reflecting their main risk factors and management strategies for CVD. The strategy that I applied gives an overview of the media representation of statins from the point of view of an academic or other external analyst, but runs the risk of not reflecting any one particular reader's consumption of news.

The second limitation is that my aim to capture all news stories in the included publications during a specific time period may have missed to represent the development of particular themes in the stories over time. This may be important due to the strong, often opposing, viewpoints that were put forward in many articles. Focusing the searching and analysis on the presentation of a few key issues, such as how the guidelines were described or how different stakeholders' arguments were communicated, could have added aspects to assessing the publicly available messages about CVD. With regards to one major theme in the interviews being that patients 'seek stability' when forming an understanding of CVD risk and medicines use, the variability of voices, viewpoints and depth of discussion of the updated guidelines comes across as possibly interesting to explore further.

### *8.3.2 Conceptual framing and planning of the empirical study*

The conceptual framing and planning of a study determines if it is designed to produce the knowledge that is needed to answer the research questions.[172] At the start of this thesis, I suggested that part of the problem with polypharmacy as a phenomenon of modern health care lies in the inconsistent knowledge about it. Although specific (medical) aspects of it are described, other possible perspectives – for example that of patients – remain uncharacterised. Therefore, this study was set up to consider the medical phenomena of polypharmacy and CVD risk management from a perspective that acknowledges both the biomedical and social aspects of medicines use.

With this aim, I planned a study that would elicit descriptions of how patients understand their own use of medicines in CVD risk management. The study was informed by reviews of scientific and lay literature, which meant my search for information was guided by other existing bodies of knowledge about different aspects of medicines use. Focusing the literature review on patients' expectations meant that I got an overview of various types of influences on how people understand and evaluate medicines. Moreover, it provided me with examples that I could use during the interviews to encourage participants to express their own views. The analysis of newspaper articles highlighted the potential tension between messages from policy-makers, information from prescribers and people's own understanding of health matters, which indicated areas to explore in interviews. Although my analysis of data was inductive, the various descriptions of medicines in CVD risk management all helped me identify and formulate questions and hypotheses that drove the process forward.

In recruitment and sampling of participants I aimed to include people with different experiences of CVD risk and use of medications. The characteristics of all included participants are shown in appendix A11. Recruitment was done via GP practices and using search criteria that would identify patients from groups of people at high and low risk for CVD. When contacting GP practices, I met with difficulties in terms of very few agreeing to help me recruit patients. This could be at least partially due to the way that primary care research is organised within the NHS, with there being incentives for primary care centres to engage in research funded by certain bodies, for example the National Institute for Health Research, NIHR (which was not funding this project). However, as the practices that actually took part were situated in different parts of Liverpool, it was possible to include patients from areas of different socioeconomic status.

Patients from both the high risk and the low risk groups responded to the invitation. Based on the information people had given in their replies, I applied maximum variation sampling to try and collect as many variations as possible of how people of different ages, genders and health were making sense of the CVD risk management medicines that had been prescribed to them.[96]

As described in chapter 5, section 5.2, this strategy produced a sample of participants that all had received a high blood pressure diagnosis at some point and had all been prescribed medication against hypertension, which they had been using for at least a few years. Different types of blood pressure medicines and statins were the most frequently mentioned ones in participants' replies to my interview questions about which medicines they used, and a multitude of aspects related to blood pressure were thus present in the data. A limitation in the sample was that all participants actually used the blood pressure medicines that had been prescribed to them – in contrast to what is often reported, no-one had rejected the medicines altogether. Another limitation was the lack of participants in the youngest age group (below 41 years) and of women at high risk of CVD and over the age of 80. This affected my ability to achieve a purposive sample with maximum variation, mainly to the effects that the interview data lacks views from women at high risk for CVD and/or high age. However, the stories and examples that were shared by participants did not seem to be bound to particular backgrounds in terms of illness and medicine-taking – participants that look “similar” in terms of sampling categories expressed very different thoughts and view during the interviews.

The presence of personal stories, opinions and thoughts about CVD risk management medicines in the group of participants that my recruitment and sampling strategies produced – despite the process failing to fill all aspects of the sampling frame – indicates that they were valid for this study. Participants' examples showed many possible understandings and meanings of CVD risk and its management, which is what this study set out to look for. In describing their own experiences, people concentrated on various aspects and made different types of connections which could help me piece together an alternative picture of CVD risk built on patients' views.

A different recruitment strategy or set of inclusion criteria could have included even more perspectives on patients' understanding of CVD risk – for example particular links to obesity, smoking or comorbidities. Concentrating my inclusion to patients of a certain age, gender or socioeconomic background could also have allowed me to produce a more detailed account of

views held by a specific group of patients. Sampling outside a medical context, like approaching people in the community, might have captured more critical voices from people that had chosen not to attend health checks or seek help from their GP for health problems, but would have diverted the focus of the study from exploring patients' use of medicines. In terms of my aims for this study – to explore a current primary care policy from a patient perspective – some diversity among the participants was preferred, since the development of CVD risk management means it encompasses many different groups of potential patients.

### *8.3.3 Truth value and neutrality*

To consider the truth value of my findings is to question how well they convey participants' understanding of the research topic – whether the different parts of my account truthfully represent the 'voices' in the data although they have been fitted together with theory and other people's stories. Since I adopted a critical realist perspective in my study, the truth value is not a measure of if the findings are true in relation to a particular definition of medicines or CVD risk management. Instead, it relates to how all the possible meanings that participants shared were incorporated into the knowledge that was created in the study.[172] The question of neutrality is about establishing that the findings represent participants' views rather than mine. Several steps throughout the research process help to ensure that the collected data is transformed into an account that, although informed by theory and literature, shows the knowledge that participants shared.

An advantage of interviews as a method is that both the researcher and the participants can use examples and explanations during the course of the interview to clarify meaning and check the understanding of questions and answers. By “using the human as the research instrument” [96] I could adapt each interview into an exploration of topics that each participant seemed to find important, and thereby gather as much information as possible in areas where people indicated that they had a lot to share. For example, I adapted my questions in the interview schedule to participants' own examples from their medical and life history. To encourage participants to share stories that would provide rich descriptions, I tried to convey my curiosity about their experiences. This was done both by emphasising that the research was about people's own views and by letting my non-verbal communication show that I was interested, surprised or impressed by what they told me.

The recording of interviews and subsequent verbatim transcribing produces 'proof' of what was said during interviews and thus gives a foundation against which findings can be checked.

As described in chapter 4, section 4.6.2 I began analysis by familiarising myself with the data though listening to recordings while reading transcripts. This process served as a check that the interview had been accurately and coherently transformed from talk to text,[172] and also allowed me to mark out where things were said with for example emphasis, hesitation or jokiness. Thereby, participants indications of things as important, difficult to describe or used as a curious story were carried into the analysis.

At the early stages of data analysis, the breadth of my interview material became evident and I decided to condense it by means of applying a coding frame in order to focus my interpretation to a few themes. A drawback of using a structured frame for condensing data (rather than open coding) might be that it limits the sensitivity to unexpected findings. However, it can also help the researcher to maintain the connection with the research question throughout the data extraction process and support the production of a useful account.[94] In my experience, the condensation of data was a necessary step to take forward the analysis. By constructing the coding frame *after* a round of open coding, using themes that were prevalent in all interviews, I would argue that my approach was useful without constraining the analysis and jeopardising its truth value.

During the steps of data analysis, I kept returning from the condensed dataset to whole transcripts so that I could review the context of extracts and thereby code them in a way that was truthful to their wider meaning. Thereby, associations were compared not only in terms of wording or what topic they were related to, but also in relation to both longer sections of transcripts, whole accounts and my field notes from the interview. Keeping the context of extracted data close at hand and going back to test my interpretation in the light of a longer narrative helped my emerging story to stay aligned with the whole stories that participants had shared during the interviews. One feature of my analysis which served as a check that my interpretive account had not taken me too far away from participants' stories was testing the thematic structure on new data. The themes, subthemes and categories that were derived from the first 14 interviews required only minor adjustments when the last four interviews were coded with it, showing that my interpretation had retained a strong relation to individual accounts of using medicines in CVD risk management.

The qualitative analysis of data is undeniably subjective, since it is done by a researcher that enters the process with a set of ideas and interests.[94] Thereby, the meaning that I see (informed by my reviews of literature and the conceptual framing of my study) quite possibly

differs from what a different researcher would find. By including a transparent account of the analysis process, I show my active role as a researcher in this particular study; in identifying starting points for the analysis, choosing important aspects and presenting the findings.[137] Since I demonstrate how the individual stories were brought together and how I moved from a descriptive towards an interpretive account (see appendix A10), I also invite the reader of my research to review the truth value and neutrality of the process of knowledge creation and the findings it produced.

#### *8.3.4 Consistency and applicability*

The assessment of consistency is the questioning of whether the findings in my study would be the same if it was repeated in a similar context – that is, whether they are stable over time and between situations. Since this study was done with a critical realist perspective, many different types of knowledge about medicines counted as knowledge. However, when knowledge is created in conversation between participant and researcher, the interaction shapes what is said during interviews and thereby what was registered as information and included in the further research process. In reviewing the consistency of my findings I will therefore critically review how my position as a researcher in relation to the participants might have influenced what they chose to tell me about CVD risk and medicines and how I understood their answers.

From participants' point of view, this study was first presented in a predominantly medical context: the invitation letter came from their GP practices, the information leaflet and reply slip were centred on health conditions and medicines, and I presented myself as a health care professional. By starting off from a point associated with a biomedical perspective I ran the risk of framing CVD risk management as an exclusively medical issue towards the participants, thereby encouraging answers describing a 'correct' way of using medicines [169] or even signalling that people who had rejected medicines were less welcome to participate. Despite these challenges, as a group of people that are at risk for CVD the participants in this study represent a variety of ages and life situations (see appendix A11 for a list of participants' characteristics).

However, during interviews I emphasised that I was interested to hear about people's own experiences, thoughts and views, and not primarily in checking which particular medicines they used or not. Some confirmation that the conversations reached beyond standardised statements was given when participants described their elaborate views on medicines and health and also pointed out that they had not discussed the medicines like this with their doctor.



My positionality – my relation to the field I am researching – also has the potential to shape the analysis that I present. Being a pharmacist with a background in drug epidemiology and health policy work, my views on actors, relations and responsibilities in the field of prescribing and use of medicines are shaped by both academic education and professional experience. The former has provided me with an understanding of the physiological mechanisms for relations between for example blood pressure and heart attacks and the statistical rationale for controlling biomarkers in populations with the aim to reduce morbidity, mortality and health care costs. The latter has shown the importance of political, social and organisational aspects around health care. For example, my professional understanding of health care as a system of professionals in an organisational context allowed for the conclusion that GPs are key actors in the future of risk management prescribing. Moreover, it has highlighted the double role of prescribers as they simultaneously treat individual patients and deliver evidence-based care to populations.

Finally, I turn to the applicability of the findings in this study on other areas of health care and use of medicines. It is done by considering some aspects of the study design as well as the character of my findings.

Taking an inductive approach in my analysis of the interview data, which started with open coding, permitted my interpretation to include what the participants themselves associated with their diagnoses and medicines. Potentially, this could make the findings more applicable to other areas, as people might have included experiences related to various medicines in our conversations, thereby sharing more of a “generic” view of medications. On the other hand, it is possible that a deductive analysis approach could have supported the applicability of findings, by actively searching for data that would be relevant also to other diagnoses.

However, the two provisional themes used in the condensation of interviews into a dataset (‘blood pressure’ and ‘medicines’ effects’) were linked to statements about CVD risk diagnoses specifically, but also to broader ideas about health promotion and prevention of disease. Since both themes contained descriptions of how individuals perceive benefit from risk management medicines, how medical information might be interpreted and what roles people see for GPs, policy-makers and the pharmaceutical industry, the further analysis produced an account that is useful in a broader examination of polypharmacy in primary care.

## 8.4 Suggestions for further research

This study has explored a particular aspect of prescribing in a particular context. However, many more factors influence how medicines are used, and aspects that were present in this study but not fully explored could add valuable knowledge about polypharmacy and patients' views on medicines.

One perspective is the relation between cultural factors such as social class or ethnicity and the understanding of medicines in CVD prevention. The prevalence of CVD varies between groups of different socioeconomic status and ethnical origin,[196-198] but the interplay between risk factors, lifestyle and life situation can be ambiguous. The strong focus on individual responsibility in relation to health and medicines that I found in this study might not appear, or appear in a different way, in different populations. Since my analysis omitted social structures as an explanatory factor, further research could test or expand the conclusions in a more socially diverse sample of patients.

This study was initially planned to compare how patients and health care professionals balanced possible benefit and harm from medicines. Since it instead came to be an exploration of different aspects of patients' views, the professional angle remains to be explored. The scoping interviews with four GPs in Liverpool present many potential starting points in themselves (see appendix A1), and they become even more interesting when related to my findings about patients' reasoning. One question to address is how health care practitioners see risk management with medicines in relation to other interventions, and how they negotiate between population and individual effects when delivering evidence based care.

A recent critical examination of the NHS Health Check programme questions its effects in terms of directing resources, predicting disease and improving outcomes for patients.[79] Valuable knowledge about structural features that contribute to prescribing and polypharmacy could come from investigating professionals' views on their role in implementing prevention policies that involve medicines. As a complement to my research on patients' understanding of medicines for CVD risk management, and in the light of the criticism, such investigations of the relations between policy and practices could add valuable knowledge about the role of medicines in modern health care.

One subject that this study has touched upon is how people engage with scientific knowledge: how patients interpret medical information and incorporate it into personal decisions and

actions regarding medicines. My findings in this area resonate with descriptions of how people interact with the institutions of science and technology that modern society is built around [41], some of which I will mention here since they could point to further research.

The incorporation of both ideas and products of biomedical science into daily life represent what Giddens [199] calls the linking of local practices with global relations. In the context of my study, this description refers to how the local, everyday use of tablets in the absence of illness symptoms becomes linked to an outcome that is globalised in the sense of time (benefit will be achieved at an unknown point of time in the future) and place (benefit will be achieved by a few patients within a treated cohort). The linking is made possible by means of acceptance of a system of knowledge that is trusted, although not fully understood. Trust is maintained through individuals' interaction with the system at so-called access points; encounters with professional representatives or tokens that inspire trustworthiness. Apart from recognising their GP's advice as important, participants in this study used the visual indications of medicines' effects as an access point – they had seen that the tablets worked, and thus accepted the context of risk, medicines and health.

Regarding the concept of risk, Beck [200] discusses how it is central to modern society. Signifying a danger that is defined by the knowledge about it, risk becomes possible only in systems of expert knowledge. Furthermore, risk represents a revealed uncertainty – something that has become a threat precisely because it has been identified. However, although scientific objectivity rules the calculation of average effects of different risks, the definitions of what is actually a harmful outcome or dangerous level is ultimately socially negotiated.[201] Experts' definition of risk, however, has only a limited meaning for individuals since average effects and measurements are not applicable to specific cases. Giddens suggests that the concept of risk indicates a multitude of possible futures, thereby implying responsibility on making choices in managing it.[202] My findings have several connections with this discourse of risk, for example patients' interpretation of the population-based prevention strategies and the understanding of a risk score as a defined condition.

Within the scope of this study, I have merely established that these theories describe my findings – or that my findings constitute an example of some of the phenomena central to the theories. Further research could make use of this connection, either by using the empirical findings to test and expand the theory or by strengthening the theoretical interpretation of my data for the purpose of suggesting implications. Questions to address could be how people

judge what health information to trust, and which aspects of prescribing that might threaten the trust that currently seems to exist.

## **8.5 Conclusions**

This study shows patients' understanding of the use of medicines in prevention of CVD. It has pointed to a strong influence of a biomedical description of health on people's views, but also highlighted how an individual perspective dominates patients' decisions and actions. Central influences on patients' views are a simplified representation of CVD risk something that will have particular consequences for the individual, anticipation of defined effects from medicines, and a personalised understanding of health information, which leads to individual responsibility for engaging with risk management.

My findings indicate how policies based on biomedical evidence might be perceived by the people whose health they are aiming to promote. Insights regarding communication around health risks and patients' formation of expectations of benefit from medicines contribute knowledge about a central part of modern health care. A partly new role for medicines in personal and professional health promotion has been presented in this thesis, together with a description of responsible patients who expect personal effects from their medications.

This exploration of polypharmacy has shown that the rationale behind extended prescribing needs to be examined with patients' views in mind, and offers a theoretically and empirically grounded account of central aspects to address.

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### Scoping interviews with GPs

The initial plan for the empirical part of this research was to compare patients' and GPs' views on the use of multiple medicines in risk management prescribing, and an exploratory study was designed in the first year of the project. Since I met with difficulties in recruiting GPs to interview, and the two literature studies that ran alongside the empirical study (see chapters 2 and 3) indicated a number of aspects to investigate within patients' understanding of CVD risk management, I decided to focus the project on patients only. However, the few completed interviews with practitioners were valuable as background material by being first-hand descriptions of how CVD risk management is applied in UK primary care today. Main topics in the GP interviews also served as statements against which patients' understanding could be compared and contrasted, and thus helped the analysis of empirical data. Here, I summarise the aspects that informed the analysis of my interviews with patients.

Four GPs in Liverpool were interviewed at the start of the empirical study; two men and two women at three practices situated in different parts of the city. In the interviews, I asked about their own experiences and practices in prescribing for the long-term management of CVD risk conditions – how they made decisions, discussed with colleagues and interacted with their patients. The GPs' descriptions entailed both examples of their own professional practices and the overall strategies they and their colleagues used in order to provide as good care as possible within their capacity. After addressing their own reasoning and prescribing, I specifically asked about their opinions on the current strategies in place for CVD risk management and how they negotiated the treatment of individual patients with overall NHS policies.

One major topic in the interviews was the use of evidence in practice. All four GPs expressed their trust in available guidelines. They mentioned that national prescribing guidelines covered clinical as well as economic aspects, and therefore supported rational prescribing. Having guidelines at hand meant medicines were not used too early or too freely. Risk stratification tools were described as helpful in assessing which patients would benefit from treatment. The documentation was also useful in explaining to patients why they should consider treatment; the GPs' experience was that most patients understood and accepted the evidence if it was presented to them.

The GPs described their strategies for motivating patients to use medicines to manage CVD risk. As this often entailed “starting someone that feels perfectly well on tablets for something *you* think is a problem”, the application of evidence-based medicine to patients sometimes required some argumentation. All found it useful to refer to the evidence in guidelines, and felt that it supported patients’ understanding of the possible benefits or simply their acceptance of the medicines when side effects occurred. Three of the GPs focused on the connection between biomarkers and disease endpoints such as heart attacks and strokes, whereas one concluded that the patients just needed to know that having low blood pressure and cholesterol was good, and having high was bad. In cases where patients chose not to use medicines, it could be convenient to stress the relation between biomarkers and outcomes: “whether their blood pressure is 150 over 90 or 135 over 70 means nothing on a day to day basis, but knowing that by having it at 130 over 70 might stop them having a stroke... there’s a gain there”.

All the GPs mentioned the media as influential on their patients’ opinions about medicines; both newspapers and information distributed online. With regards to CVD risk management, this sometimes resulted in patients’ preferring non-pharmacological interventions over taking tablets. Weight management, smoking cessation support and advice for physical activity was available to their patients and promoted as an addition to medicines. Here, the impact of socioeconomic circumstances was cited; reaching well-informed and health-conscious patients in affluent areas was contrasted with providing care for patients who “are sat at home smoking and drinking, with lots of social problems as a consequence”. Despite the difference in level of deprivation between the areas where they worked, all the GPs saw primary care as the foremost stakeholder in improving people’s health.

A recurring theme was the GPs’ reliance on the evidence that is included in clinical guidelines for CVD risk management. In terms of *how* decisions and recommendations were made, their descriptions suggested that the evidence is applied to individuals, rather being used as a resource for responding to individual needs. One GP expressed the consideration of benefit and cost-effectiveness it like this: “If you’d do it for the NHS, then you do it for each patient too.” Benefits with early detection and active management were expressed on both micro and macro levels; they included influencing individual’s risk for disease as well minimising the number of unplanned hospital admissions so that the practice’s performance compared well in benchmarking of outcomes.

### Published review and synthesis of scientific literature

A paper based on my review and synthesis of literature on patients' expectations of medicines was published in Health Expectations; see overleaf.

# Patients' expectations of medicines – a review and qualitative synthesis

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## Abstract

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**Background** An increasing part of prescribing of medicines is done for the purpose of managing risk for disease and is motivated by clinical and economic benefit on a long-term, population level. This makes benefit from medicines less tangible for individuals. Sociology of pharmaceuticals includes personal and social perspectives in the study of how medicines are used. We use two characterizations of patients' expectations of medicines to start forming a description of how individuals conceptualize benefits from risk management medicines.

**Search strategy and synthesis** We reviewed the literature on patients' expectations with a focus on the influences on expectations regarding medicines prescribed for long-term conditions. Searches in Medline and Scopus identified 20 studies for inclusion, describing qualitative aspects of beliefs, views, thoughts and expectations regarding medicines.

**Results** A qualitative synthesis using a constant comparative thematic analysis identified four themes describing influences on expectations: a need to achieve a specific outcome; the development of experiences and evaluation over time; negative values such as dependency and social stigma; and personalized meaning of the necessity and usefulness of medicines.

**Conclusions** The findings in this synthesis resonate with previous research into expectations of medicines for prevention and treatment of different conditions. However, a gap in the knowledge regarding patients' conceptualization of future benefits with medicines is identified. The study highlights suggestions for further empirical work to develop a deeper understanding of the role of patients' expectations in prescribing for long-term risk management.

## Background

Prescribing of medicines is one of the most common interventions in medical health care in

the UK. Most prescriptions are issued in primary care and the annual cost for these exceeds £8 billion.<sup>1</sup> Best practice for identifying persons at risk for disease, controlling symptoms,

preventing acute events and managing sequelae is outlined in treatment guidelines. Early detection and treatment can be crucial in certain conditions. However, lowered thresholds for diagnosis of conditions associated with risk for future disease and the subsequent increase in treatment of such conditions introduce medicine-taking to a large number of patients for whom the individual benefits are less obvious.<sup>2,3</sup> Examples of this are medicines that target elevated blood pressure or cholesterol, which are among the most commonly prescribed in the UK today.<sup>4</sup>

Awareness that the rising rates of prescribing for management of risk are accompanied by growing health-care costs, widespread polypharmacy and more medication errors has led to efforts to improve the quality and safety in prescribing.<sup>5</sup> The format of guidelines,<sup>6</sup> style of medical practice<sup>7</sup> and effectiveness of interventions directed towards key patient groups<sup>8</sup> are areas that have been targeted – all of which are concerned with the prescriber or the system in which doctors and patients interact. These medicines management strategies tend to mention patients' views as important to consider,<sup>9</sup> but retain a theoretical focus that limits the understanding to one based on medical definitions of health, illness and medicines.

Patients' usage of medicines can be seen as taking place at an intersection of medical science and daily lives. A vast body of knowledge in medical sociology describes many aspects of the interaction between people and medicines. Theory spans from individuals' compliance with medical instructions<sup>10,11</sup> via characterizations of the role of medicines in daily life<sup>12,13</sup> to considerations of the whole-systems influences from patients, medical professionals, health-care organization and governance.<sup>14–17</sup>

Treatment for the purpose of management of risk for disease often targets asymptomatic conditions that require long-term commitment by patients for potential beneficial effects to be demonstrable. One factor contributing to such commitment could be patients' expectations of future benefits or risk limitation arising from the prescribed medicines. In a theoretical description of the influences on patients' expectations on medicines, Thompson and Sunol emphasize the combination of cognitive and affective components and outline a range of personal and social factors that interplay with the information provided in a health-care context.<sup>18</sup> These include needs, values, experiences and emotions, as well as social norms, conditions and restrictions. Four types of expectations are identified: Ideal, predicted, normative

**Box 1** Classification of patients' expectations suggested by Thompson and Sunol<sup>18</sup>

Type of expectations	Characteristics
Ideal expectations	Desired or preferred outcome based on idealistic beliefs regarding what a medicine can provide
Predicted expectations	Anticipated, realistic outcome based on personal or vicarious experience and other sources of knowledge
Normative expectations	What the patient thinks should or ought to happen, based on evaluation of what is deserved or socially endorsed
Unformed expectations	Inability or unwillingness to formulate what is expected due to fear, social norms or lack of knowledge

Health-care context-specific features that influence expectations

Long-term relation between patient and doctor  
 Patient's emotional state may be shaped by illness experience and coping strategies  
 Patient's knowledge about the condition and the effects of medicines may be very limited at the outset of a treatment, but increases over time  
 Patients tend to use a subjective rather than objective set of notions when evaluating effects and services



**Box 2** Search terms

Research question	Search terms	Hits
What are the influences on patients' expectations regarding prescribed medicines?	expect*AND influence* AND patient* AND prescribing OR prescription	614
	expect*AND patient* AND primary care AND prescribing OR prescription	135
	influence* AND qualitative research AND prescribing OR prescription	427
What benefits do patients expect from medicines prescribed for long-term prevention of disease?	benefit* AND expect*AND qualitative research AND prescribing OR prescription	225
	benefit*AND expect* AND medicine* AND patient* AND prevent*	122

and unformed (see Box 1). Patients' expectations regarding medicines for a number of long-term conditions are described by Pound *et al*<sup>19</sup> in a meta-ethnography of lay experiences of medicine-taking. The authors mention a number of tangible effects that are used by patients while evaluating medicines by means of balancing of risks and benefits. The latter is composed of hopes for what medicines shall do: relieve or control symptoms, avoid relapse or hospitalization, slow or halt disease progression, prevent future illness or bring normality.

Guided by these descriptions, we want to contribute new knowledge regarding patients' expectations of medicines prescribed for the purpose of management of risk. An empirical study is in progress. In the review and synthesis of literature reported here, we draw on qualitative work on long-term medicine-taking to start building an understanding of patients' expectations that is not limited to a medical definition of what medicines can and will do. Our research questions were 'What are the influences on patients' expectations regarding prescribed medicines?' and 'What benefits do patients expect from medicines prescribed for long-term prevention of disease?'

## Methods

### Search strategy

The database searches were set up to explore possible influences on patients' expectations of medicines. We used broad search terms to capture multiple aspects of our research questions. The database searches were then done by UD

in two stages. The first step explored influences on patients' general expectations related to prescribed medicines. To find out specifically about treatments for the management of risk for future disease, the second step focused on patients' ideas about benefits with medicines prescribed for preventive purposes. Search terms are outlined in Box 2. Searches were performed in Medline and Scopus during August and September 2013 for publications from all available years.

### Selection of publications

The first step in the selection was scanning of article titles. Abstracts and full-text articles were then checked by UD for descriptions of patients' accounts of using medicines and descriptions of influences on expectations. Due to the exploratory nature of this review, quality of the reported study was not used as a criterion for inclusion or exclusion. Instead, a careful examination of the applicability of the reported findings to the area of long-term treatments was undertaken at the selection and synthesis stages. This assessment was done by UD with support from JR and TW. Articles were included in the review if they explicitly addressed qualitative aspects of patients' expectations, beliefs, views or thoughts about medicines prescribed for treatment or prevention of long-term conditions and were written in English. Publications retrieved in the searches but excluded during the review process described practices or behaviours rather than views, professionals' expectations rather than patients', evaluations of specific interventions or solely

quantitative aspects of patients' expectations. Articles about end-of-life care or medicines used for lifestyle or aesthetic purposes (obesity, facial acne, hair loss) were also excluded, on the basis that expectations related to these types of treatments are likely to be influenced by emotional factors that lie outside the scope of this research.

#### Extraction and synthesis of data

Data extraction and synthesis was done by open coding of reported influences on patients' expectations in the selected literature followed by a constant comparative thematic analysis<sup>20</sup> and synthesis.<sup>21</sup> Included articles were read closely to pick up data that was related to our research questions, and descriptive codes were allocated to pieces of text. The coding process was informed by, but not limited to, the aspects of patients' expectations on medicines discussed by Thompson and Sunol and Pound *et al.*<sup>18,19</sup> Codes were grouped together into categories that were adjusted as the analysis proceeded. By comparing extracts with the whole data set, including examination of cases that contradicted or deviated from the rest, the analytical categories were aggregated into themes that captured both general and specific aspects and similarities as well as differences in the dataset. The synthesis allows for themes to be formulated at a level 'beyond' description of the different types of data in separate studies so that new interpretations and explanations can be suggested. The extracted data together with contextual characteristics for the included studies are summarized in Table 1.

UD undertook the searches and selection of publications and the initial open coding and synthesis. Discussion between UD and JR strengthened the interpretive validity by identifying areas of dissonance or uncertainty and refining the developing categories. All three authors participated in finalizing the themes. The criteria for trustworthiness proposed by Lincoln and Guba were used as a framework for the critical assessment of the emerging analysis.<sup>22</sup>

## Findings

Combinations of the search terms in titles or abstracts yielded 1428 unique records. After scanning of article titles, 92 abstracts were reviewed and 27 full-text articles assessed for inclusion. Reference lists in the reviewed papers were scanned for useful sources, which returned 23 more publications. The final synthesis included 20 publications, 12 of which were identified via databases and eight from the scanning of references. The selection process is outlined in Fig. 1.

Four themes were identified from our synthesis of the literature, see Table 2. Influences on patients' expectations on medicines range from being highly specific and related to short-term targets that medicines are hoped to help achieve to general views on whether medicines are useful at all. Practical experiences, personal beliefs and other people's opinions are influential as expectations are formed and develop over time.

#### A need to achieve a specific outcome

Expectations can be determined by the need to bring about a specific change. Medicines as an instrumental way to relieve both specific and wide-ranging aspects of symptomatic illness are elicited by patients with depression needing to get better quickly after 'hitting rock bottom',<sup>23</sup> and epilepsy, where the medicines control seizures as well as reduce worry.<sup>10</sup> Preventive medications are also seen as providing very specific benefits such as 'stopping a heart attack' or 'curing the bones'.<sup>24,29</sup> These anticipations resemble a combination of the ideal and predicted expectations described by Thompson and Sunol.<sup>18</sup> More general descriptions of medicines as effective tools to care for oneself beyond what can be obtained with diet and exercise are shared in interviews with patients suffering from heart failure and osteoporosis.<sup>25,27</sup> In terms of expressing expectations, it has been suggested that this is predominantly done by patients looking for specific outcomes, especially in relation to a condition that greatly impacts on their daily lives.<sup>24</sup>

**Table 1** The dataset

Authors (year)	Content
Schofield <i>et al.</i> (2011) <sup>23</sup>	<p><b>Context</b> Semi-structured interviews with 61 patients recruited from GP practices in three areas in the UK. Eligible patients invited via a letter from their GP. All participants had been prescribed antidepressants against depression and/or anxiety for at least a year. Purposive sampling is used to reflect the population of users of antidepressants in terms of age, sex, ethnicity and socio-economic background. Most participants had experienced several episodes of depression at the time of the interview.</p> <p><b>Findings</b> <ul style="list-style-type: none"> <li>• At the time of initiation of treatment, medicines were seen as a short-term measure to get better at a time when they really needed it.</li> <li>• Many participants had reservations against antidepressants when first consulting their GP, due to concerns about using medicines in the long-term, fear of addiction and negative views held by themselves or others.</li> <li>• Using and experimenting with medicines over time makes patients experts on their own conditions and treatments. This expertise gives the patient more control over decisions regarding management of their illness.</li> </ul> </p>
Conrad (1985) <sup>10</sup>	<p><b>Context</b> In-depth interviews with 80 people with epilepsy about the meanings of medications in everyday life and why medicines are taken or not, carried out as a part of a larger project about living with epilepsy. All participants were or had been using medications against the condition. Recruitment was done via community channels. Participants are described as between 14 and 54 years old, mostly lower middle class and coming from urban areas in the United States. Interviews were held independent of medical and institutional settings.</p> <p><b>Findings</b> <ul style="list-style-type: none"> <li>• Peoples' practices regarding medicines are related to aspects of control in two directions: taking control over symptoms or worries about the disease, or being controlled by a disease that forces usage of medicines.</li> <li>• A continuous evaluation of the medicines is undertaken, and patients may stop taking them if no specific effect is perceived.</li> <li>• The author refers to a general view in society that it is better to try to achieve health goals without medicines, and reports reflections of this view in the participants' accounts.</li> </ul> </p>
Dolovich <i>et al.</i> (2008) <sup>24</sup>	<p><b>Context</b> The study aims to investigate expectations and influences thereon to find out if expectations have an impact on how medicines are used. Purposive sampling and recruitment through community and health-care channels in Canada were used. The 18 participants represent different ages, living conditions and types of medicines used. Semi-structured interviews were conducted around the medicines the participant considered most important and analysed using grounded theory.</p> <p><b>Findings</b> <ul style="list-style-type: none"> <li>• Expectations are most clearly expressed by patients who want a clearly defined outcome in a condition that affects their daily life.</li> <li>• Participants are realistic in what they want medicines to achieve and use different sources of information to adapt and confirm their expectations.</li> <li>• The number of medications used every day was described as an issue; either as burdensome for an individual or in general terms.</li> </ul> </p>
Unson <i>et al.</i> (2003) <sup>29</sup>	<p><b>Context</b> With a stated aim to increase adherence, patients' beliefs about osteoporosis (OP) medication and medicines in general are assessed. Focus groups based on ethnicity was recruited via senior centres and housing estates in deprived areas in the United States. A convenience sample of 55 women aged 60 years or older participated. Most participants were on prescribed medication, but not for OP. Authors suggest that what is handled as a dichotomous question (treatment or not) in medicine is a more complex decision for patients, where heuristics, moral aspects and power relations are at play.</p>

Table 1 Continued

Authors (year)	Content
	<p>Findings</p> <ul style="list-style-type: none"> <li>• Side-effects are considered serious and on a short-term basis; 'they can be worse than the disease itself' and '25% protection without side-effects is better than 50% with'.</li> <li>• Participants use both their own experiences and those shared by others in decisions about medication.</li> <li>• Participants expressed scepticism regarding prescribers' knowledge about how medicines affect specific patients and saw prescribing partly as doctors' experimentation.</li> </ul>
Granger <i>et al.</i> (2013)	<p>Context</p> <p>Mixed methods study aiming at exploring theoretical linkages between symptom experience over time and the meaning of medication adherence. Ten patients with chronic heart failure completed questionnaires measuring beliefs, behaviours, symptoms and satisfaction and were interviewed about the meaning associated with medicines. Patients were recruited by research nurses during an admission to a US university hospital with exacerbation of their condition.</p>
	<p>Findings</p> <ul style="list-style-type: none"> <li>• Experience of symptoms influences the meaning attributed to medicines.</li> <li>• Medicines are described in positive ways as tools to care for oneself, but also with negative notions of being inevitable if wanting to avoid death.</li> <li>• Patients were questioning how a large number of medicines everyday can be helpful.</li> </ul>
Mazor <i>et al.</i> (2010) <sup>25</sup>	<p>Context</p> <p>Telephone interviews with women <math>\geq 65</math> years that fulfilled WHO criteria for osteoporosis recruited from a multispecialty practice in Massachusetts, United States. History of dispensed prescriptions was used to classify participants into three groups of equal sizes: not using medication, started but discontinued medication and currently on medication. The study links core beliefs about medicines to patients' views on perceived need, safety and efficacy of a medication.</p>
	<p>Findings</p> <ul style="list-style-type: none"> <li>• The need and usefulness of medication is described as related to age, but with different conclusions: old age and brittle bones make medicines necessary, or offset the efficacy of medicines.</li> <li>• Patients that make use of peers' knowledge or experience of the medication are sceptical to treatment.</li> <li>• Connects participants' views on medicines with their core beliefs about health and illness.</li> </ul>
Nair <i>et al.</i> (2007) <sup>26</sup>	<p>Context</p> <p>Semi-structured interviews seeking to investigate patients' experiences with risk-benefit assessment when making decisions about treatment for type II diabetes. The 18 Canadian patients used different types of treatment and were recruited through community and health-care channels. Both purposeful and theoretical sampling was used to ensure inclusion of patients that found treatment easy as well as difficult. The interpretation of the interviews was validated in a focus group session towards the end of the analysis process.</p>
	<p>Findings</p> <ul style="list-style-type: none"> <li>• Avoidance of medication may be based on the impression that one is already taking too many medicines.</li> <li>• Duration of illness and experimentation with medicines influences the understanding of the effects of disease and the treatment.</li> <li>• Patients develop a personalized understanding of the value of a treatment, and this forms a basis for the decision on whether to use a medicine.</li> </ul>
Smith <i>et al.</i> (2000) <sup>35</sup>	<p>Context</p> <p>Experiences, concerns and willingness to participate in decision making about medicines were explored and compared between patients with the three conditions. Group interviews were arranged via voluntary organizations for each condition in the UK.</p>

Table 1 Continued

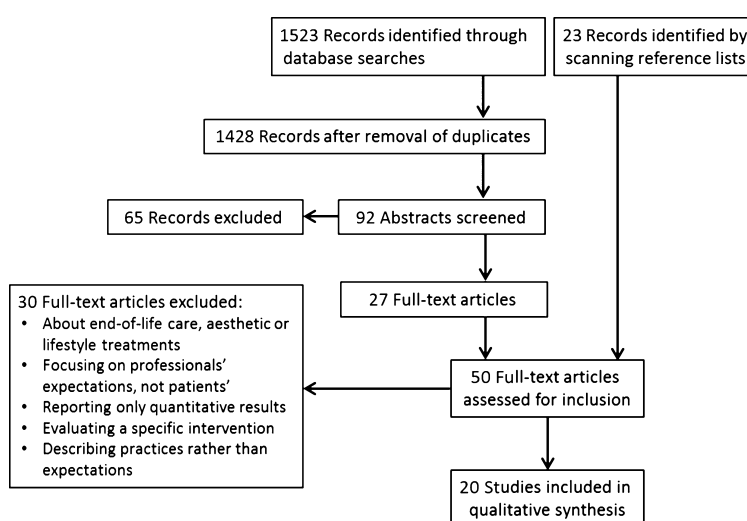
Authors (year)	Content
	<p>Findings</p> <ul style="list-style-type: none"> <li>• Patients with schizophrenia had experienced medicines as a way for doctors to modify their behaviour in order to be acceptable in society.</li> <li>• Patients wishing to leave decisions about medicines to doctors still wanted to be informed about positive and negative effects so that they could monitor their treatment.</li> <li>• Information about medicines is used to participate in decisions and challenge doctors.</li> </ul>
Cranney <i>et al.</i> (1998) <sup>30</sup>	<p>Context</p> <p>In an investigation of barriers to implementation of guidelines for hypertension treatment, UK healthy elderly patients' and GPs' perceptions of risks and benefits were addressed. Participants recruited via a GP practice (75 patients) and on a training course (121 GPs). Attitudes to risk with untreated hypertension and ideas about benefit from prescribed medicine were assessed with questionnaires accompanied by visual aids during semi-structured interviews.</p> <p>Findings</p> <ul style="list-style-type: none"> <li>• Most patients overestimate both the risk with untreated hypertension and the benefit from preventive treatment and accepted treatment based on trusting their doctor.</li> <li>• When provided with information about the clinically proven relative risk reduction, fewer patients accept treatment and more patients mention the risk of side-effects.</li> <li>• Communicated ideas about benefit with treatment are rather vague and based on conceptions of prevention being necessary or helpful in general.</li> </ul>
Leaman and Jackson (2002) <sup>31</sup>	<p>Context</p> <p>Questionnaire completed by 216 patients from a single GP practice in the UK. A random sample of patients, stratified for age and gender, were asked to state the level of benefit requested for acceptance of a first, second and third medicine for treatment of hypertension. Benefit was represented with fixed levels of NNT(5). Hypothetical scenarios explaining the consequences of a myocardial infarction and some practical aspects of the treatment accompanied the questionnaire, and respondents were asked to answer with only these aspects in mind.</p> <p>Findings</p> <ul style="list-style-type: none"> <li>• Patients request a much higher level of benefit than what has been clinically proven.</li> <li>• Authors mention patients' lack of rationality in making decisions about medicines, leaving decisions to doctors and altered circumstances when facing a real rather than a hypothetical situation as explanations for why so many patients are on treatment for hypertension despite the results in the study.</li> </ul>
Fuller <i>et al.</i> (2004) <sup>32</sup>	<p>Context</p> <p>Older people's attitudes to stroke prevention were examined by presenting probabilities of risks and benefits with warfarin treatment. People aged 66–97 years answered questionnaires about hypothetical scenarios of risk reduction and practical aspects of treatment. The 81 participants were recruited via an elderly medicine outpatient clinic at a large university hospital in the UK.</p> <p>Findings</p> <ul style="list-style-type: none"> <li>• Participants expressed wishes for a guaranteed number of years of disease-free survival in order to engage with medicine-taking.</li> <li>• Experiences of disease in the family and personal health beliefs are influential on the acceptance of treatment.</li> </ul>
Hux and Naylor (1995) <sup>33</sup>	<p>Context</p> <p>Data on benefit of lipid-lowering medication from a large clinical study were presented in different formats (relative and absolute risk reduction, NNT, average and stratified survival) to 100 participants aged 35–65 recruited from an outpatient setting in Canada. Treatments were presented as free of charge, without side-effects and suggested by a doctor in hypothetical scenarios. Participants' preferences and their stated certainty about the decision were recorded to investigate how the format of benefit data influences decisions about treatment.</p> <p>Findings</p> <ul style="list-style-type: none"> <li>• Relative risk reduction generated the highest acceptance for treatment, followed by absolute risk reduction.</li> <li>• Stratified survival data were preferred over average numbers.</li> </ul>

Table 1 Continued

Authors (year)	Content
Arnell <i>et al.</i> (2013) <sup>34</sup>	<p>Context Experiences, attitudes and expectations about information given prior to starting anti-TNF therapy were assessed in focus group interviews with ten rheumatoid arthritis (RA) patients in the UK. All participants were currently on treatment and purposively sampled to represent different ages, disease duration and activity and anti-TNF agent used. Data were analysed with a phenomenological approach.</p> <p>Findings</p> <ul style="list-style-type: none"> <li>• Patients described a willingness to face increased cancer risk due to treatment if sustained relief from RA symptoms could be achieved.</li> <li>• Fear of disease symptoms and long-term effects influenced the desire to start and stay on anti-TNF medication; side-effects were considered secondary.</li> </ul>
Gale <i>et al.</i> (2012) <sup>36</sup>	<p>Context Meta-ethnography of qualitative literature on usage of medication for prevention of cardiovascular disease, seeking to explore variations in behaviour and implications for practice.</p> <p>Findings</p> <ul style="list-style-type: none"> <li>• The context for patients' decisions about medicines goes beyond the clinical setting – social interactions in the personal community, other people's experiences and various sources of information are influential.</li> <li>• Doctors are trusted sources for information about medicines; information from academia, pharmaceutical companies and media is less trusted.</li> </ul>
Sale <i>et al.</i> (2011) <sup>28</sup>	<p>Context A phenomenological study conducted to investigate patients' experiences with the decision to take OP medication after sustaining a fracture. Participants aged over 65 years who had had a fracture in the last five years and were at high risk for having another one were recruited via an OP screening programme in Canada. Two-thirds of the 21 patients were currently taking OP medication. Cost for medication was covered by a local drug plan for all participants.</p> <p>Findings</p> <ul style="list-style-type: none"> <li>• A decision to use or not to use medicines is often not permanent; patients report they have changed their mind about medicines or might do it later.</li> <li>• The decision to start OP medication is often based on trusting the prescriber's recommendation.</li> <li>• Discussing the decision about medicines with friends or family or searching information elsewhere often resulted in not accepting treatment.</li> </ul>
Adams <i>et al.</i> (1997) <sup>37</sup>	<p>Context Attitudes of patients with asthma to prophylactic medication are explored with a patient-centred perspective. In-depth interviews were carried out with 30 participants recruited from a GP practice in Wales. Participants represented different ages, social backgrounds and duration of asthma.</p> <p>Findings</p> <ul style="list-style-type: none"> <li>• Using medication every day is closely linked to the idea of having a disease.</li> <li>• Those patients that accepted the treatment as part of living with asthma still disliked using medicines every day.</li> <li>• Negative views on steroids, associated with illicit use, were overcome by the fact that they are needed by the patient and prescribed by a professional.</li> </ul>
Stack <i>et al.</i> (2008) <sup>38</sup>	<p>Context Patients' beliefs about multiple medicines are addressed in interviews with 19 patients diagnosed with cardiovascular disease and type II diabetes. Authors acknowledge that usage of many medicines is associated with poor adherence and self-management in patients. Recruitment was done via two urban GP practices in the UK.</p> <p>Findings</p> <ul style="list-style-type: none"> <li>• Diabetes medicines are seen as necessary, whereas medicines for the management of cardiovascular risk, especially lipid-lowering agents, are given lower status.</li> <li>• The patients that describe a perceived risk for cardiovascular events have experienced heart attacks or strokes among family or friends.</li> </ul>

**Table 1** Continued

Authors (year)	Content
Marshall <i>et al.</i> (2006) <sup>39</sup>	<p><b>Context</b> Relations between level of cardiovascular risk, acceptance of treatment and demographic characteristics were investigated quantitatively. Patients without diagnosed cardiovascular disease from GP practices in the UK were invited to participate in coronary risk screening and a research study. Preferences regarding treatment in hypothetical scenarios were recorded from the 181 participants before the screening, and a second interview was conducted afterwards to see whether patients changed their minds when told about their own risk.</p> <p><b>Findings</b> <ul style="list-style-type: none"> <li>• Patients' preferences are stable over time but vary between individuals.</li> <li>• A difference in acceptance of treatment between patients from different social classes is suggested to be related to ideas about moral obligation to use medicines.</li> </ul> </p>

**Figure 1** PRISMA diagram of search results and selection of publications.

The need for confirmation of a medicine's effect by symptom relief or some other immediately observable benefit is an often mentioned theme in relation to patients' expectations on medicines. Correspondingly, a lack of salient effect from the medicines may lead to loss of perceived meaning with the therapy in patients' views. This phenomenon points to the link between medicine-taking and relief of symptoms being an important motivator for patients.<sup>10,19,26,27</sup>

Patients' expectation that medicines will obtain certain effects also seems to apply to outcomes defined by someone other than the patient; both as a general 'they should do what the doctor says need to be done'<sup>24</sup> and more specifically mentioned by people with schizo-

phrenia saying that medicines are used by doctors to control patients' behaviour and make it acceptable to society.<sup>35</sup>

In relation to expectations on medicines for risk reduction, several studies report that patients overestimate the possible benefits with preventive treatments: The requested reduction of risk for cardiovascular events and stroke in return for the effort of taking medicines every day is much higher than clinically available, and when provided with information about the likely level of benefit, patients tend to decline treatment referring to potential side-effects.<sup>30,31</sup>

In interviews with elderly patients about their willingness to use anticoagulants to prevent stroke, patients discussed the decision in terms of gambling and trade-offs and expressed



**Table 2** Codes and themes

Theme	Examples of codes
1. A need to achieve a specific outcome	Medicines relieve symptoms, help avoid hospitalization, control disease or improve the conditions of daily life <sup>10,23–25</sup> Confirmation of effects is sought, and lack of identifiable effects can lead to the medicine being seen as not useful <sup>10,24,26,27</sup> Medicines offer something beyond what is achieved by diet and exercise <sup>25,28</sup> A medicine prescribed for prevention 'stops a heart attack', 'cures the bones' or 'does the job the doctor says need to be done' <sup>24,29</sup> Benefits with preventive treatments are overestimated <sup>30,31</sup> Patients wish for guarantees of survival <sup>30–33</sup>
2. Experiences and evaluation develop over time	Duration of illness influences understanding of disease and treatment effects <sup>26,34</sup> Past bad experiences of side-effects triggers a conscious evaluation of risks and benefits when new treatments are suggested <sup>26</sup> Patients are seeking to confirm and adjust expectations <sup>26,28</sup> One's own experiences and those of other people are used in decisions about medicines <sup>24,25,28,29,34–36</sup> Risks and benefits are balanced by patients in a different way than by doctors <sup>26,29–32</sup>
3. Negative values – dependency, criticism and social stigma	Fear of getting addicted, associations with illicit substance use <sup>23,37</sup> Hesitancy to be dependent on medicines for a normal life <sup>10,37</sup> The number of medicines used by one person can be seen as too high <sup>26,27</sup>
4. A personalized meaning of medicines; their necessity and usefulness	Medicines for different conditions are seen as being of different value <sup>38</sup> Patients with the same condition express diametrically different views about the treatment: necessary or of very limited value; as something that helps to live normally or the only way to avoid death; as a choice based on experience or a resignation in lack of other options <sup>23,25,37</sup> Core health beliefs and notions of responsibility and morality influence decisions <sup>24–26,39</sup>

wishes for a guaranteed number of disease-free survival years.<sup>32</sup> The format of risk and benefit information when suggesting treatment for the management of risk seems influential on patients' decisions about treatment: Relative risk reduction yields much higher acceptance than number needed to treat (NNT) and disease-free survival stratified between groups of patients gave more positive responses than when presented in a summarized way.<sup>33</sup> The representation of benefits by absolute or relative risk reduction might be interpreted by patients as giving everyone a reduced risk, whereas with NNT, one single person gets the whole benefit of survival, making it less appealing. An expressed desire for a guaranteed number of years and the gambling and trade-off language used by patients in discussions of the decision to accept or decline treatment also suggest that benefit is being conceptualized as an entity.

#### Experiences and evaluation develop over time

The expectations placed on medicines seem to be influenced by previous experiences of illness and medicine usage.<sup>10,26</sup> Predicted expectations<sup>18</sup> dominate. These are weighted together in a continuous evaluation of whether and how to use the prescribed medicines and longer duration of illness seems to open up for a more nuanced description of expectations. A cyclical trial and evaluation, where patients balance their view on long-term medicine-taking with important experiences of improvement and worsening of their condition, make patients experts on their own treatment.<sup>23</sup> This evaluation includes factors from the medical realm such as information about the condition, possible consequences and prescribed medicines as well as factors from other parts of life. In comparison with medical professionals' evaluation of medicines' appropriateness, patients use a



shorter time-scale when determining whether a medicine has beneficial effects. Their acceptance of risks or symptoms in relation to side-effects and the number of aspects weighted into decisions also make patients' decision making different from that stipulated by a biomedical model of health and illness.<sup>29,34</sup>

Aside from patients' own experiences, information from surrounding people is reported by several authors as influential on expectations. Doctors' advice<sup>30,35</sup> is balanced with personal and vicarious experiences,<sup>25</sup> whereas academics and pharmaceutical industry are seen as less reliable sources.<sup>36</sup> Development of trust in a prescriber seems to influence patients' decision to accept treatment, suggesting that it leads to expectations of beneficial effects,<sup>28,36</sup> while patients that retain a more critical stance compare prescribing to experimentation and question the doctor's knowledge about how a specific patient's body works.<sup>29</sup> Consulting peers seems to be associated with patients being reluctant to accept treatment.<sup>28,29</sup>

Patients' balancing of perceived beneficial and harmful effects changes over time.<sup>26,28</sup> Even patients that want their doctors to make decisions about treatments state a desire to be informed about the anticipated effects to participate actively in evaluation of the effects. Information for this purpose is also sought from public sources and the health-care system to confirm and adapt expectations.<sup>24</sup>

### Negative values – dependency, criticism and social stigma

The third theme encompasses negative aspects of medicines that are not derived from personal experience but instead related to general, societal views. It contains aspects of normative and unformed expectations.<sup>18</sup> Certain types of medicines are described by patients as associated with addiction, dependency and illicit substance usage. Patients with asthma describe negative associations evoked by illegitimate use of steroids by bodybuilders and depressed patients hold initial reservations about treatment due to fear of addiction and social stigma. Patients

describe both their own views, those of family members and reports available in the public realm as negatively influencing usage of medicines.<sup>23,37</sup>

The number of medicines used by one person is also reported as something that may be valued negatively and evoke criticism from others. Patients question the helpfulness of taking a large number of medicines every day<sup>27</sup> and may decline new suggested therapies on the basis that they are already using too many medicines.<sup>26</sup>

### A personalized meaning of medicines; views on their necessity and usefulness

The fourth theme is built up by codes related to the utility of medicines in patients' lives, beyond that of providing immediate effects. This encompasses longer periods of time and wider aspects of living with illness. A recurring feature in the data set was the widely contrasting views patients share in relation to medicines' usefulness and necessity. This theme displays a combination of the four types of expectations described in Box 1.

When diagnosed with a chronic condition such as asthma or epilepsy medicines can play the role of either aids to obtain normality, by giving the patient control over symptoms, or obstacles cutting one off from normality by their association with social stigma and having an illness. However, such negative notions can be overcome by acquiring knowledge about a condition: Steroids form an essential part of the management of asthma, and medication against depression or epilepsy becomes accepted as a way to get on with life.<sup>10,23,37</sup>

A number of authors address the question about whether medicines are seen as necessary for life, health, etc. or if usage is optional, subject to personal inclination and should be balanced with life style changes to help manage the condition. Patients with multiple conditions may regard some medications more necessary than others, or some as being essential and other optional.<sup>38</sup> In interviews with elderly women about osteoporosis medication, some

participants stated that the medication was an inevitable, normative way to treat a condition associated with old age and therefore it would be effective, whereas others claimed that the natural ageing of the bones would limit the effectiveness of medication. In more general terms, prescription medication was described both as a way to obtain something beyond what diet and exercise could bring and as a 'last resort' that would only be used if those failed.<sup>25</sup>

In several studies, medicines are described as a commitment and 'part of life' by patients with chronic conditions. However, this can have both positive and negative connotations. Heart failure patients interviewed about their associations with medicines report taking them without knowing what benefits they will bring but 'because I don't ever get better' or 'otherwise I will die'. On the other hand, the medicines also allow patients to 'complete things during the day' and 'enjoy doing more things'.<sup>27</sup> Similarly, depressed patients described the decision to use medicines in the long-term as a conclusion based on experience, or as resigning to them being the only way to get by.<sup>23</sup>

One way to reconcile the opposing views expressed by patients living with the same chronic condition is the conclusion that expectations on medicines are influenced by deeply held personal views. This is described in terms of core beliefs about health and illness and feelings of responsibility or obligation to use medicines when diagnosed with a condition.<sup>26,28,39</sup> Links between acceptance of treatment and demographic characteristics such as level of education or social class have been addressed and discussed by a few authors, but with inconclusive results.<sup>31,39</sup>

## Discussion

Our analysis identified four themes regarding influences on patients' expectations of medicines: a need to achieve a specific outcome; the development of experiences and evaluation over time; fear of dependency and social

stigma; and personalized meaning of the usefulness and necessity of medicines. The desire for observable short-term effects, usage of experiences and knowledge in a process of evaluation and notions of meaning linked to personal and societal values show that expectations on medicines are multidimensional and dynamic. A low acceptance for side-effects, fear of dependency on medicines that do not have addictive properties and criticism against using a high number of medicines every day are influential factors that fall outside the biomedical model of health and illness.

In the specific case of expectations of benefit from medicines that are prescribed to manage asymptomatic risk conditions, our findings highlight a number of issues for consideration. Patients' desire for tangible benefits and specific outcomes in theme 1 and the role of experiencing ill health and medication effects in theme 2 point to a potential lack of meaningful ways to relate to and engage with medicine-taking when the reason for treatment is a risk identified by one's doctor. An implication of this may be that patients interpret a decision about using such medicines as a dichotomous choice rather than as a way to influence the likelihood of outcomes. Another aspect is the perceived need for and acceptance of treatments for a growing number of conditions related to risk for future disease. Themes 3 and 4 point to possible issues regarding patients' acceptance of the concept of risk reduction by means of treating cohorts to decrease the number of acute events in a population. Prescribing of several medications to manage, for example, blood pressure may be considered medically appropriate if there is evidence for possible benefit from all of them. However, patients' views that it renders a number of daily tablets that is 'too high' or that higher blood pressure is part of ageing challenge the notion of benefit. In a wider sense, the increased availability and prescribing of medicines that target risk for future disease might influence personal and societal values held about using medicines for preventive purposes.

Influences identified in our analysis mirror the ideal, predicted, normative and unformed expectations described by Thompson and Sunol<sup>18</sup> (see Box 1) and show how patients engage in practical evaluation of medicines as described by Pound *et al.*<sup>19</sup> By combining one review and 17 primary data collections from several clinical fields that assess different qualitative aspects of medicine-taking, we broaden the description of influences on patients' expectations on medicines. Our synthesis progress the understanding of patients' expectations by highlighting the importance of evaluation of medicines from an individual perspective. This finding is important for the further development of a theoretical description of medicines used for the purpose of risk management.

Codes and themes also resonate with an investigation of the impact of long-term medicine-taking on quality of life published just after the searches for this analysis were undertaken.<sup>40</sup> There, the authors identify wishes for tangible effects, usage of different sources of information to confirm expectations, trusting or challenging recommendations from one's doctor, fear of dependency and complex decision making regarding the usage of a necessary but disliked medicine. Our study adds weight to the findings of Krska and colleagues by identifying these themes across a range of data sets.

Methodological limitations of the presented synthesis stem from the fact that although all the three authors were active in the decisions about searches and extraction as well as the coding and formulation of themes, the practical work was done mainly by one researcher. During the database searches, it became clear that 'expectations' is used liberally in the literature and it was difficult to specify narrow search terms that captured exactly what we were looking for. For this reason, it became apparent that searching reference lists of the included articles was also an important way to identify publications. Other limitations are due to the diverse nature of the primary data in the included publications, which is derived from narratives, interview material and data

collected via questionnaires and describe both personal experiences and statements about hypothetical scenarios. Although the connection between using medicines and living with a long-term medical condition has been highlighted,<sup>10,37</sup> only a few of the included publications discuss this issue in relation to their findings. This makes it difficult to determine whether the data represent specific expectations on medicines or thoughts about health, illness and care in general. An example of this is the discussion of a relation between readiness to make a decision about starting treatment and acceptance of it in a couple of the included publications, where the decision-making process may be hampered by a patient's ambivalence vis-à-vis the diagnosis or the prescriber in clinical cases, and by difficulty to relate to the task in a hypothetical situation.

Assessment of truth value, applicability, consistency and neutrality helps determine the usefulness of findings in qualitative research.<sup>22</sup> The recursion of codes and themes between this synthesis and other investigations of qualitative aspects of patients' views on medicines is an indication of good truth value and consistency of the results. However, the neutrality may be compromised by the fact that most of the included publications, although researching qualitative aspects of expectations, adopt at medical model where the aim to increase adherence to treatment becomes evident in the conclusions. Applicability of findings may differ between clinical fields. With regard to long-term management of risk, the reviewed literature contains descriptions of some elements that relate to patients' decisions to accept or decline medicines. However, gaps remain in the theoretical understanding of how benefits with such medications are conceptualized, and how this may interrelate to prescribing for such purposes. This gap will be addressed in new empirical research. We are currently undertaking a study exploring patients' expectations on risk management medicines in an area where prescribing is high due to health policies' focus on early intervention, cardiovascular disease.

## Conclusions

Unwanted effects of the increasing prescribing of medicines in the UK are the growing burdens of medication-related problems, waste and costs for patients and the NHS. In addition to interventions framed as medicines management, addressing the social aspects of health, illness and medicines could offer a way to understand and address more aspects of the increasing levels of prescribing in primary care in the UK.

The stochastic nature of usage of medicines for the purpose of risk management, where time to beneficial outcome and distribution of benefit in a group of treated individuals are impossible to predict, makes patients' conceptualization of benefits an interesting and important but also under-researched element of prescribing. Whereas medical and economic arguments for risk management medications can be gathered on a population level, findings in this qualitative synthesis suggest that individual patients are influenced by many more types of knowledge and values in a continuous, personal evaluation of whether to start and continue using medicines.

A deeper exploration of how patients conceptualize benefits with medicines prescribed to manage risk is the objective of our next study, involving interviews with patients at different levels of risk for cardiovascular disease. Building on this review, the aim will then be to develop a fuller theoretical understanding of how this topic can contribute to improved usage of medicines.

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## Conflicting interests

The authors have no conflicting interests to report.

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Letter of ethical approval



**Health Research Authority**  
**National Research Ethics Service**

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28 June 2013

**Miss Ulrica Dohnhammar**  
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Dear Miss Ulrica Dohnhammar

<b>Study title:</b>	<b>Exploring patients' and GPs' views on the balancing of benefits and risks with multiple medicines usage</b>
<b>REC reference:</b>	<b>13/NW/0387</b>
<b>Protocol number:</b>	<b>UoL000963</b>
<b>IRAS project ID:</b>	<b>128757</b>

Thank you for your email of 27 June 2013. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 19 June 2013.

**Documents received**

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Participant Information Sheet	2	25 June 2013

## Approved documents

The final list of approved documentation for the study is therefore as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Evidence of insurance or indemnity: University of Liverpool		02 August 2012
GP Invitation Letter	1	26 April 2013
Interviewers Guide	1	26 April 2013
Investigator CV: Ulrica Dohnhammar		01 April 2013
Investigator CV: Dr Joanna Lucy Reeve		
Investigator CV: Professor Tom Walley		
Letter from Sponsor: Sponsorship Approval Letter		26 April 2013
Letter of invitation to participant	1	26 April 2013
Other: Project Information for Newspapers	1	01 May 2013
Other: Sampling Framework	1	26 April 2013
Other: Study Ended Letter	1	26 April 2013
Other: Critical Events Protocol	1	26 April 2013
Participant Consent Form	1	26 April 2013
Participant Information Sheet	2	25 June 2013
Protocol	1	29 April 2013
REC application: 128757/445385/1/772		08 May 2013
Reviewers' Comments		26 April 2013

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

<b>13/NW/0387</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely



**Ms Josephine Foxall Dant**  
**Assistant Co-ordinator**

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**Copy to:** Dr Joanne Reeve  
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Alex Astor  
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Kirsty Pine  
Cheshire and Merseyside Comprehensive Local Research Network

**Invitation letter**

**(Practice notepaper)**

Dear \_\_\_\_\_

[Name of practice] is taking part in a local research study where researchers are trying to find out more about experiences of using multiple medicines. We are doing this so we can provide care and support for those that do so. To find out more about how it is to use medicines, the researchers need to talk to as many people as possible so that they can hear a wide range of views.

I am writing to you to invite you to take part in the research study. Along with this letter is a leaflet that tells you why it is being done and what will be involved for you if you decide to take part. This is to help you decide whether or not you wish to take part in the research. If you want to take part, you just need to return the questionnaire on the next page and send it back to the researchers. You may then be contacted by Ulrica Dohnhammar, a research student at the University of Liverpool, who will interview all participants in the study.

Please take as much time as you like to read the leaflet and discuss it with your family, friends or your GP here at the practice. This letter also includes a copy of the consent form that tells you what the researchers will ask your permission to do with the information that participants share with them. If you have questions or need more information about the study and how you can take part, please don't hesitate to ask Ulrica. Her contact details are:

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telephone: 0151 795 5325  
e-mail: [ulrica.dohnhammar@liverpool.ac.uk](mailto:ulrica.dohnhammar@liverpool.ac.uk)

If you would like to take part in the study, please fill in the short questionnaire and send it back to Ulrica in the stamped addressed envelope enclosed.

[Signature]





## Balancing Benefits and Risks with Multiple Medicines

a research study

Patient Information Leaflet

## Balancing Benefits and Risks with Multiple Medicines

You are being invited to take part in a research study. It is important for you to understand why the research is being undertaken and what it will involve before you decide whether to participate. Please take time to read the following information carefully and feel free to discuss it with anyone you wish.

We are very happy to answer any questions if anything is unclear or you need more information. You do not have to accept this invitation and should only take part if you would like to.

Thank you for taking the time to read this.

### **1. What is the purpose of the study?**

A lot of people are taking many medicines every day to treat health problems and prevent future disease. Beside the good effects of the medicines, doing this can bring difficulties: Medicines may interfere with each other, and the risk for side effects increases.

Besides how the medicines affect your body, they may also influence how you can live your daily life. By including these perspectives in the research we want to learn about how people take positive and negative aspects of health into account when deciding how to use medicines.

We are interested to hear your thoughts about using your medicines – how you expect them to help you, what worries you might have about your health and medicines and how you have tackled difficulties related to this. In a similar way, we will ask GPs about how they include balancing of positive and negative effects when prescribing medicines.

### **2. Why have I been invited to take part?**

We want to talk to adults who are prescribed medicines that prevent heart problems. The GP practice that you are registered with has agreed to help us invite people among their patients to the study.

Only persons who understand verbal or written explanations in English will be eligible to take part.

### **3. Do I have to take part?**

It is entirely up to you if you want to take part. Whether or not you decide to join the study, this will not affect any of your medical care.

### **4. What will happen if I do join the study?**

If you decide to take part in the study, please fill in the questionnaire that you got together with this leaflet. Send them through the post to us, using the stamped addressed envelope.

A researcher will then contact you to arrange for an interview. The interview will take place in a location that is convenient for you.

During the interview we want to hear about your views on positive and negative effects of using your medicines. We will ask about your experiences and how taking multiple medicines fits in with your life. The interview is expected to last for about an hour. None of the information that you share with us will be passed to your doctor or pharmacist.

Before the interview starts, we will ask you to sign a form stating your informed consent to participate in the study.

With your permission, we would like to record the interview so that we don't have to take notes but can focus on listening to what you are telling us. The recording will be typed up to make a transcript of the interview. This transcript will be anonymised so that no personal details which could identify you are left.

Analysis of the transcripts will produce the results from the study.

**All the information you give us will be in the strictest confidence.**

### **5. What are the downsides of taking part?**

We are asking you to set aside time to fill in the questionnaire and to meet us for an interview of about one hour. In finding a time and place for the interview we will be as flexible as possible so that the arrangement suits you, but we understand that it might not be practical for you.

During the interview, we will ask you about positive and negative experiences that you have had from your health condition and your medicines. Some people find this upsetting to talk about.

If you do become upset or unwell, we will ask your permission to get in touch with your GP so that they can provide you with the necessary help and support.

## **6. What are the benefits in taking part?**

By taking part, you can help us find out more about how people balance positive and negative effects with medicines when deciding how to use them. Hearing and analysing many peoples' experiences gives the research team an opportunity to identify issues that need to be addressed, and suggest ways for improvement so that more people can use medicines in a way that is meaningful to them.

Although the findings may not help you directly, other people who have taken part in similar studies have found it interesting and enjoyable to share their views on health and medicines.

## **7. What if I am unhappy or there is a problem?**

If you have any concerns or problems with the study, please contact the project lead, Ulrica Dohnhammar, to discuss them. Her contact details are at the back of this leaflet. If you require a formal response to your concern, we would ask you to write to us clearly stating the issues you wish to

raise. We will respond to this letter within two weeks.

If you remain unhappy or have a complaint which you feel cannot be made directly to the research team, then you should contact the University of Liverpool Research Governance Officer on 01510794 8290 or [ethics@liverpool.ac.uk](mailto:ethics@liverpool.ac.uk). When contacting them, please provide the name of the study and the researcher so that they can be identified, and the details of the complaint you wish to make.

## **8. Will details about me and my participation in the study be confidential?**

All information given for the study will be in the strictest confidence and handled in accordance with the Data Protection Act (1988).

Researchers on the study have no access to any of your personal details until you have sent us the questionnaire as a confirmation of your wish to take part.

If you decide to join the study your personal details given on the questionnaire will be stored securely, accessible only to the research team. They will be destroyed within three years of the end of the study. All data from the interviews will be anonymised before being stored securely. Only members of the research team will know who the data is from. Only anonymised data will be used in the analysis stages of the study.

### **9. What will happen to the results of the study?**

The results of the study will be based on our analysis of the anonymised data from all the interviews. The findings will be published so that as many as possible can benefit from them. We will therefore present the study and its findings at conferences and in academic journals.

Since this study is part of doctoral research training, the findings will also be included in the final thesis presented to the University of Liverpool.

A summary of the results will be sent to everyone who takes part in the study. We will also send reports to the University of Liverpool and to the Research Ethics Committee.

No report will include any identifiable information or personal details about anybody that has taken part in the study. The final report may contain quotes from interviews so that we can give examples of what people told us. These quotes will also be anonymised, so that nobody reading the report can know what you have said during your interview.

### **10. What happens if I want to leave the study?**

You are free to leave the study at any time, and without giving an explanation. If you decide to leave the study after we have interviewed you, you can ask for the data to be destroyed.

### **11. Who is organising and funding the study?**

Ulrica Dohnhammar, who is a health professional and research student, is leading the study. She is responsible for all aspects of the coordination and management of the research.

If you decide you want to join the study you may be contacted by her.

Other members of the research team are Dr Joanne Reeve, a GP and Senior Clinical Research Fellow at the University of Liverpool and Tom Walley, Professor of Clinical Pharmacology at the University of Liverpool.

The study has been approved by the National Research Ethics Service Committee North West, Haydock (Ref: 13/NW/0387). The University of Liverpool is funding the research.

### **12. Who can I contact if I want more information?**

If you have any questions, need any more information or would just like an informal chat about the study, please contact:

Ulrica Dohnhammar

Health Services Research, University of Liverpool  
Waterhouse Buildings Block B  
1-5 Brownlow Street  
Liverpool L69 3GL  
Telephone 0151 795 5325  
[ulrica.dohnhammar@liverpool.ac.uk](mailto:ulrica.dohnhammar@liverpool.ac.uk)

**Thank you for reading this leaflet.**



## Consent form

### Balancing benefits and risks with multiple medicine

**Researcher:** Ulrica Dohnhammar, University of Liverpool

**Chief Investigator:** Dr. Joanne Reeve, University of Liverpool

1. I confirm that I have read and understood the information leaflet dated 1 July 2013 for the above study. I have had time to consider the information, ask questions and have them answered satisfactorily. ☐
2. I understand that my participation is voluntarily and that I am free to withdraw at any time without giving any reason. ☐
3. I understand that the information I share with the researcher will be recorded and that the recording will be transcribed to produce a full account of the interview. ☐
4. I understand that anonymised quotes may be used in reporting of the study, and I agree to this. ☐
5. I understand that the recording of my interview will be saved for up to three years after the study has finished, and will then be destroyed. ☐
6. I give permission for the transcript of my interview to be kept for ten years in anonymised form, and potentially used in future research. ☐
7. I agree to take part in the above study. ☐

_____ Name of participant	_____ Date	_____ Signature
_____ Member of the research team taking consent	_____ Date	_____ Signature

### Questionnaire for the study “Balancing benefits and risks with multiple medicines”

By filling in and returning this questionnaire to the research team, you declare your interest to participate in the study.

#### 1. Please provide your contact details so that the researchers can get back to you:

Name: \_\_\_\_\_ Telephone: \_\_\_\_\_

Address: \_\_\_\_\_ Postcode: \_\_\_\_\_

#### 2. Please tick the boxes that best describe you:

Age:    18 - 40 ☐      41 - 60 ☐      61 - 80 ☐      81 or over ☐

Gender:    Female ☐      Male ☐

#### Number of medicines that I take on a daily basis:

No medicines ☐      1-5 medicines ☐      More than 5 medicines ☐

#### If I think about my ability to do daily tasks such as walking about or doing housework...

I can do what I want ☐

I need some help with it ☐

I need help with most things ☐

#### Thinking about my emotional well-being I would say that...

I mostly feel good ☐

I feel a bit anxious or depressed sometimes ☐

I feel anxious or depressed most of the time ☐

**Please continue on the next page→**



**3. Please describe your current health:**

**What health problems do you have?**

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**If you have heart problems, for how long have you had them?**

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**Thank you! Please send this questionnaire back to the research team:**

Ulrica Dohnhammar  
Department of Health Services Research  
Waterhouse Buildings  
1-5 Brownlow Street  
Liverpool L69 3GL

An addressed and stamped envelope is enclosed.

### Sampling framework

Sampling of patients was done in two steps.

**Step 1:**  $n$  (expected)  $\approx 300$ . Identification of eligible patients by searches in practice databases for individuals matching the inclusion criteria.

**Step 2:** Purposive sampling among patients that have expressed their interest to participate in the study,  $n \approx 30$ . Distributed as evenly as possible over the following categories:

Parameter	Indicator	
Age	18-40 years	
	41-60 years	
	61-80 years	
	+ 81 years	
Gender	Female	
	Male	
Disease status	Recent diagnosis	Single condition
	Long-standing health conditions	Multiple conditions
Health status	Good on both indicators	
	Mixed	
	Bad on both indicators	
Prescribing status	No medicines	
	1-5 medicines	
	more than 5	

## Interview schedule; original and final versions

This is the first version of the schedule for the semi-structured interviews with patients.

Questions and prompts	Aspect to be explored
<p>I'm interested to hear about your experiences of taking several medicines every day. Could I start by asking you what different medicines you take?</p> <p>Which are they?</p> <p>What are they for?</p> <p>Do you take them all at the same time or are they spread out over the day?</p>	<p>How are the medicines described?</p> <p>How do they fit in with daily activities?</p>
<p>How long have you been taking this one?</p> <p>Did anything happen that made you go to your doctor?</p> <p>Have you had to change anything about how you live your life?</p>	<p>Was the condition diagnosed in conjunction with screening or an acute event?</p> <p>Is treatment described as the only option to deal with the condition, or as one method among others?</p>
<p>Can you tell me a about this one (choose one that is recently started or was started in relation to an event of some kind) – what was it for again?</p> <p>Did you and your doctor discuss the idea behind using this medicine before you started it?</p> <p>Do you remember what you were told about the medicine?</p> <p>How have you been since you started taking it?</p> <p>Have you talked to your doctor about how it goes?</p>	<p>Have the anticipated benefits and risks been discussed explicitly?</p> <p>Has this been followed up?</p>

Question and prompts (continued)	Aspect to be explored (continued)
<p>When it was suggested that you start with this medicine, did your conversation with your doctor cover what you wanted to know or did you talk to other people as well?</p> <p>How much did you want to know?</p> <p>Did you read about it on the internet?</p> <p>Did you ask family members, friends, social groups, other patients at the surgery?</p> <p>Did you ask the chemist, read the package leaflet, look in a BNF book?</p>	<p>Are popular or scientific media used as resources? What impressions or conclusions seem to come from that?</p> <p>Does peer groups or patient groups influence the individual's perception of what the medicine can or will do for them?</p>
<p>If you compare living with your (condition) and living with taking the medicines every day, would you say it is "worth the effort" to take the medicines?</p> <p>Do you feel or think that the medicines are helping you?</p> <p>Is it a large number of pills to take every day?</p> <p>Has your opinion changed over time?</p>	<p>Is a conscious balancing of benefits and risks done? Which factors are taken into account on each side?</p>
<p>In the research project we are investigating how people deal with taking many medicines every day, and particularly how they go about balancing the pros and cons with their health conditions and medicines. Is this something that you can relate to from how you handle your medicines?</p>	<p>Are benefits and risks described in similar terms? Does there seem to be an active participation in the decision to use medicines? If so, how does it manifest itself?</p>
<p>Is there anything you would change about your medicines if you could?</p>	<p>Open question to capture any opinions evoked by the topic of the interview.</p>

This is the final version of the interview schedule. Updates were informed by practical experiences, such as adaptation to how people tended to start describing the medicines they were taking and my increasing confidence in conducting interviews. It was also influenced by the emerging analysis: my questions got a more pronounced focus on the concept of risk and the personal understanding of how the medicines are beneficial. Additions are marked in italics.

Question and prompts	Aspect to be explored
<p>I'm interested to hear about your experiences of taking several medicines every day. Could I start by asking you what different medicines you take?</p> <p>Which are they?</p> <p>What are they for?</p>	<p>How are the medicines described?</p> <p>How do they fit into daily activities?</p>
<p>How long have you been taking this one?</p> <p>Did anything happen that made you go to your doctor?</p> <p>Have you had to change anything about how you live your life?</p> <p><i>Why did your doctor say you needed this one?</i></p>	<p>Was the condition diagnosed in conjunction with screening or an acute event? Is treatment described as the only option to deal with the condition, or as one method among others? How was the link between the medicine's effect and the risk for future events described by the doctor?</p>
<p><i>Did you want to know about the medicine before starting to take it? How did you go about?</i></p> <p><i>What did your doctor say about it?</i></p> <p>Did you read about it on the internet or in the papers?</p> <p>Did you ask family members, friends, other patients at the surgery?</p> <p>Did you ask the chemist, read the package leaflet, look in a BNF book?</p>	<p>Have the anticipated benefits and risks been discussed explicitly?</p> <p>Has this been followed up?</p>
<p><i>What is it like to be at risk for heart problems?</i></p> <p><i>Personal feeling/knowledge vs. medical information?</i></p> <p><i>Accept/question/doubt the condition?</i></p> <p><i>Do you have to treat it?</i></p>	<p>How is the risk condition described in 'own words'? Are people responsible for engaging with treatment of risk??</p>

Question and prompts (continued)	Aspect to be explored (continued)
<p>What good do you think or feel the medicine is doing for you?</p> <p><i>How are you feeling now – has anything changed?</i></p> <p><i>Do you think the medicine is helping you?</i></p> <p><i>Is there anything particular that has influenced how you think about the medicines?</i></p> <p><i>How did your doctor choose which medicine you needed?</i></p>	<p>How are possible benefits from medicines described in ‘own words’, and how are they related to risks?</p>
<p>Do you feel that you are balancing pros and cons with the medicines?</p> <p>Is it a large number of pills to take every day?</p> <p>Has your opinion changed over time?</p> <p>Is it worth the effort to take medicines?</p> <p><i>Which things are you taking into account?</i></p>	<p>Is a conscious balancing of benefits and risks done? Which factors are taken into account on each side?</p>
<p><i>What effect are you looking for? What would tell you that the medicines are working?</i></p> <p><i>Feeling good</i></p> <p><i>Test results</i></p> <p><i>How do present effects link to future outcomes?</i></p>	<p><i>Returning to the question about benefit, with a focus on the personal experience and how it informs thoughts about future outcomes.</i></p>
<p>Is there anything you would change about your medicines if you could?</p>	<p>Open question to capture any opinions evoked by the topic of the interview.</p>

## Description of the analytical process

In this appendix, I give my account of my data analysis; how I created new knowledge about medicines in CVD risk management by combining the research participants' stories into one theoretical description. For the purpose of transparency (and thereby trustworthiness of my analysis) I display the intermittent products of analytical steps: from the initial inductive open coding via data condensation and iterations of coding and critical review, to the formulation of a final, interpretive framework.

### Inductive open coding

The initial open coding for any data that said something about the research question and how participants made sense of CVD risk and risk management (see chapter 4, section 4.6.2) generated a diverse collection of descriptive categories, which are shown in a slightly condensed form in figure A10.a.

Category	Illustrative data – quotes, field notes, analytical comments
Measuring and visualising – technological references	<p>“You can do the Q test yourself, it’s on the internet.”; “Nowadays the doctor doesn’t just test your cholesterol before giving you statins, they do many more tests.”</p> <p><i>Risk calculations are described as accessible, normalised.</i></p> <p>“It is strange that the doctor trusts blood pressure readings, because they can vary so much.”</p> <p>“Measuring the pressure once at the surgery is a bit nonsensical.”</p> <p>“Why is your first blood pressure reading high when you measure it at home, where there are no white coats around?”</p> <p><i>Sense-making around the processes of assessing blood pressure.</i></p> <p><i>Blood pressure seems different from other conditions – even people that come across as being used to sorting health matters out for themselves and tell me that they ‘know their bodies’ indicate that the blood pressure is somehow located closer to the medical context or professionals than to their own life.</i></p>
Health	<p>“There’s nothing the doctors can do for me at this age anyway.”</p> <p><i>People focus on doing something about conditions – indicates activity, agency, direction, responsibility.</i></p> <p style="text-align: right;"><i>(continues overleaf)</i></p>

	<p>“Some people use medicines as a way to get away with eating fatty things – that’s awful.”</p> <p><i>There is a ‘right way’ to be healthy – eat well and exercise. Same as the public health message! (interview with Joyce)</i></p> <p>“We are lucky to be healthy at this age, with the help from medicines.”</p> <p><i>Using medicines is not a sign of ill health but a way of being healthy.</i></p> <p><i>Knowledge about one’s body is achieved through medical facts, not experience?(interview with Fred)</i></p> <p><i>Is it the experience of ill health that makes people balance things? If so, treatment suggested to people at low risk might be accepted with less criticism?</i></p> <p>“Other than my heart being partly dead, I’m in perfect health.”</p> <p><i>There is a division between medical conditions and health.</i></p>
Decision-making	<p>“I would question the doctor, if there was a problem to talk about” <i>So being treated for risk is not something that is seen as questionable?</i></p> <p>“We don’t use medicines because we want to, but because we have to.”</p> <p><i>Who determines the necessity? (interview with Rose)</i></p> <p><i>It is the doctor’s job to judge whether treatment is needed – they’ve got the education, and medicines are serious things so their knowledge is necessary.</i></p>
Risk	<p>“High blood pressure bothers me, it’s a condition that could shorten my life.”</p> <p>“It is just high blood pressure; could have been something that affected my ability to move about and live my life.”</p> <p><i>The concept of risk does not seem relevant to him – things do not exist until they happen! (interview with Tobias)</i></p>
Medicines in general	<p>“Medicines are becoming more and more sophisticated.”</p> <p>“Other people take medicines just because the doctor says so.”</p> <p>“All the way from when we were cave men and romans, people have wanted to take medicines and potions.”</p> <p>“Other people want quick fixes for their health.”</p> <p><i>Examples of how others want quick fixes, but no-one saying they would want one, even though many seem afraid of what their high blood pressure will lead to.</i></p>
Medical information	<p>“You shouldn’t trust the newspapers, discuss it with you doctor instead.”</p> <p>“I read all the leaflets and mark up important parts.”</p> <p>“I never read the leaflets, it scares you too much.”</p> <p><i>(continues overleaf)</i></p>



	<p>“Sometimes you get to know too much about the tablets; you can start believing that you’ll get all the side-effects.”</p> <p><i>Is information from doctors not scrutinised in the same way?</i></p> <p><i>No-one mentions guidelines – doctors and pharma are present but not the actor between them.</i></p>
Blood pressure	<p>If it is found out you have it, you take tablets for life.</p> <p>“Everybody knows that having high blood pressure is a bad thing.”</p> <p><i>Guidelines (and related information, such as the media discussion) define the concept of blood pressure.</i></p> <p><i>How come that blood pressure seems to be so accessible in language (people talk easily about their own)? It is hidden inside the body, only detectable with doctors’ equipment! Who has the ownership and responsibility for it? Is it – and the decisions about it – handed over to the professional in the clinic?</i></p>
Contradictions	<p>One patient saying both “I don’t believe the risk calculations are true for me” (<i>challenging biomedical model</i>) and “Obviously it is better to lower my blood pressure to a normal level, so I take the medicines” (<i>accepting biomedical model</i>)</p> <p><i>Where does the motivation come from; why does he accept medicines despite not seeming to believe the rationale? (interview with Nathan)</i></p>

Figure A10.a Early categories of descriptive and interpretive labels. Extracts from field notes and my analytical comments are indicated in italics.

From this broad material, it became evident that I needed to condense the data before any further analysis would be meaningful. The focus on a few aspects would help me in two ways. Firstly, it would keep the analysis centred on my research question and thereby contribute new knowledge regarding the research problem I set out to address. Secondly, it would use the potential of the qualitative methods to produce an interpretive account rather than a descriptive one, and thereby contribute to the theoretical understanding of patients’ views of medicines. As described in chapter 4, section 4.6.3, I constructed a coding frame by combining my research question with provisional themes from the open coding.

### Constructing a coding frame

Initially, I built the coding frame around the provisional theme of ‘blood pressure’. The first 14 interview transcripts were coded line by line in their entirety with this frame. However, it

was difficult to apply it in consistent way. If I took an inclusive stance, the participants' statements about medicines, CVD risk and risk management quickly became too diverse and wide-ranging to be captured within it.

If I took a stricter approach to the coding, it appeared I had to leave too much interesting information outside. For example, information about CVD risk was entwined with information about medicines; they seemed to define each other and it was difficult to separate understandings of the condition from understandings of medicines' effects.

Since the coding process felt ambiguous at this stage, I kept a record of the interesting but 'left over' data. After a while the list was so rich that I started to look for additional provisional themes that could expand the analysis and gather more of the information that participants had indicated as important.

Most of the extracts described some aspect of the medicines people were taking; how they worked (or not) and what they did to help with the CVD risk that had been diagnosed. As patients' understanding of the prescribing of medicines was a core topic for my study, I decided to use 'medicines' effects' as a second provisional theme. The final version of the coding frame, with which I again coded the first 14 transcripts, is shown in chapter 4, section 4.6.3.

### **Categorising data**

The coding generated a dataset centred on the main issues for the study (a diagnosis closely related to prevention policies and patients' views, and experiences and expectations of medicines), yet encompassing multiple angles so that the advantages of the interview method were used (capturing new and multiple explanations based within and outside the biomedical model).

To start forming an interpretive account of my data, I reviewed the coded extracts using the constant comparative technique (see section 4.6.5). Early categories were formed around reactions to and understanding of the blood pressure diagnosis, which types of knowledge that people use when making decisions and how treatments are evaluated. The first structure of 22 categories related to 9 themes is shown in figure A10.b. At this stage, some data extracts was allocated to a theme but not yet placed in a category.

Theme	Categories
Early reactions	Finding out
Contextualising	Causes
	Consequences
	Cohort features
	Explanations
	Un-allocated
Disease or not	Hidden
	It is a disease
	It is not a disease
	Levels
Knowledge types and sources	Heuristics
	Internalised biomedical view
Reasoning	Early reactions
	Long-term evaluation
	Un-allocated
What to do	Interaction between person and medicines
	What the doctor says
	Personal belief
Effects	At present
	On outcome
Long-term evaluation	
Questioning	

Figure A10.b The first category structure.

To examine my emerging findings, I started writing an account of them. As discussed in chapter 4, section 4.6.6 the writing tests the explanatory strength of the structure and content of the analysis. The writing highlighted many reasons for reviewing and questioning the first thematic structure, as it pointed to areas where data was too diverse within categories or where data about a particular phenomenon had ended up in multiple places.

One example was my problem with allocating data extracts that alluded to cohort features – were they about the risk or the medicines? Questions like this were resolved by going back to the transcripts and critically reviewing quotes in their full context. Reminding myself of the circumstances around data extracts helped me to find new possible thematic associations and move data around accordingly. As long as the category structure did not harbour all the

descriptions in a straightforward way, without overlaps or ambiguities, I kept reviewing the relations between the data extracts and my emerging interpretation. The writing and re-structuring of data in categories were parallel processes that informed each other.

An issue that took long to resolve, was my initial consideration of whether participants regarded hypertension as a disease or not. The various coded descriptions of reasons for the blood pressure to be high, how it affected daily life, what it might lead to in the long term and what could be done about it both suggested and denied that it was a disease; see figure A10.c.

<b>It is a disease</b>
<p>“It is a <i>health related</i> medical condition” – <i>setting high blood pressure apart from other less serious conditions</i></p> <p>“it could shorten my life” – <i>tangible consequences, disrupting biography</i></p> <p>“the sensible side kicks in and you do something about it” – <i>needs to be addressed; indication for medicines</i></p>
<b>It is not a disease</b>
<p>“I would be a very bad patient” – <i>having high blood pressure does not make him a patient at present</i></p> <p>“perhaps it is only natural to have higher blood pressure as you get older” – <i>i.e. it is not an indicator of something being wrong</i></p> <p>“My blood pressure varies a hell of a lot during the day and maybe they just caught me at the wrong moment or the right moment I don’t know but there we are” – <i>there is an element of chance in the process of determining whether the blood pressure is high; not a clear boundary between well and ill</i></p>

Figure A10.c. Contrasting data regarding whether high blood pressure is a disease or not. My analytical notes are displayed in italics.

However, these categories later dissolved as my questioning of how it could make sense led towards other, more meaningful and explanatory associations between the data extracts. A tangible example was how participants emphasised the need for some intervention towards high blood pressure, no matter whether their descriptions indicated that it was a disease or not. This finding drew my attention to another important division among participants’ stories about CVD risk and medicines; that between control and uncertainty. Many patients stressed that once the medicines showed that the blood pressure or cholesterol was stable, the ‘problem’ was resolved. Their examples indicated that conditions associated with CVD risk are only a problem when they are not kept under control.

To further explore the notion of certainty and uncertainty as a defining factor, I critically reviewed the data in all categories to really separate out understandings of ‘the risk condition’ itself, and the managed risk. These two themes became the starting point for a re-structuring of my analytical structure. After further testing of my emerging ‘researchers’ story’ by means of writing and critically reviewing, adjusting and condensing the data and categories, I had generated an explanatory structure for influences on patients’ understanding of medicines in CVD risk management. Four subthemes show patients’ reasoning around the concept of being at risk, and two outline how they ascertain control over the risk. The final thematic structure is shown in table 5.2 (page 87).

A final round of coding of the last four interviews required no further adjustments, and so I considered the analysis finished and proceeded to write the final version of my account, which is presented in chapters 5 and 6.

### Participants' characteristics

To provide some context for the quotes that accompany my findings, I present the characteristics of each participant in the study in table A11.1 (see overleaf).

### **Comments regarding how the information was collected and is displayed**

Participants are displayed in the order in which the interviews were done. The information in the table corresponds to categories in the sampling frame which I used to ensure that I included participants with as many different experiences and life situations as possible.

Most categories (age, gender, number of medicines, physical and mental wellbeing, self-reported health status) were included in the questionnaire that patients sent back to me to declare their interest in participating in the study (see appendix A7). The 'risk level' category corresponds to my sampling for patients at both high and low risk. It was not in the questionnaire, but assigned by me based on what diagnoses and events people told me about.

Participants' descriptions of their current health status are displayed in their own wording, as it was written in the free text sections of the questionnaire.

The statement to capture self-reported physical wellbeing was formulated as 'If I think about my ability to do daily tasks such as walking about or doing housework...' followed by the alternatives 'I can do what I want' (displayed in the table as A), 'I need some help with it' (B) and 'I need help with most things' (C).

Similarly, the statement regarding mental wellbeing was formulated as 'Thinking about my emotional wellbeing I would say that...' followed by 'I mostly feel good' (displayed in the table as a), 'I feel a bit anxious or depressed sometimes' (b) and 'I feel anxious or depressed most of the time' (c).

I have also included extracts from my field notes from each interview, showing the context I perceived around the interview. This indicates my impression of each participant and my own frame of mind from each interview – something that shaped the conversations as they took place and also supported (by means of challenging or confirming what was said) my later analysis.

Table A11.1 Participants' characteristics

Name (pseudonym)	Age group	Current self-reported health status	No. of meds	Wellbeing		Risk level		My reflections during the interview
				Physical	Mental	High	Low	
Holly	41-60	Hypertension, psoriasis arthritis, kidney disease, frequent urinary tract infections, asthma.	>5	B	a		X	I get the feeling it's not the first time she has been interviewed about using medicines. This might have to do with how she tells me things; unbroken narratives that have clear beginnings and ends. She seems to know what she thinks and feel confident that it's her way of dealing with things.
Richard	61-80	High blood pressure, slowly worsening arthritis, poor memory. I'm quite fit and active (for my age).	1-5	A	a		X	This participant wants to know if any medications that will improve memory are being developed. He seems happy to talk to me – it's a day out.
Albert	61-80	Slightly elevated blood pressure, cholesterol elevated, ulcer control has been needed.	1-5	A	a		X	This man emphasises his scientific outlook on health – he sounds genuinely factual when he describes his thoughts. He apologises for not having particularly strong views about taking medicines.
Anthony	61-80	Arthritis, COPD and cardiac. Heart problems: 8 years approx.	>5	B	b	X		He seems excited to be in the study, but a little nervous. But he is open – starts talking about his health before I ask any questions. He seems to have thought about and pondered over medicines before.  <i>(continues overleaf)</i>

Nathan	41-60	Hypertension, high cholesterol, otherwise fit.	1-5	A	a		X	He is interested in knowing how my research is going to be used and how it fits in with the health care system. He describes his own reasoning about health and medicines – spanning medicalisation, pharmaceutical industry’s influence over prescribing and mechanisms of action for medicines. I get a weak feeling that he is testing an idea about a possible link between a chest problem and a drug with me, but I do not elaborate on it.
Gerald	80+	Breathing, walking, heart, cancer (melanoma spots & lung). Heart problems: Seventies?*	>5	A	a		X	This man lives in sheltered accommodation. He has hearing problems and says he will forget what we talked about the minute I walk out the door. Difficult to get a conversation going, as he does not elaborate on his views about medicines.
Rose	61-80	None that I am aware of.	1-5	A	a		X	One of the ‘worried well’ that has taken time to think about her tablets. I get the sense that she wants to help me with the research as best she can. During the conversation she gets interested in the idea that people can have so different views of medicines – she will talk with her friends about it later.
Alfred	61-80	Hypertension.	1-5	A	a		X	A relaxed but professional conversation. I get the feeling that he wants to hear my opinion on his problems with side effects, but avoid saying anything about them.  <i>(continues overleaf)</i>



Norman	61-80	Angina, high blood pressure, arthritis (ankles, knees, wrists). Heart problems: approx. 4 years	1-5	A	a	X		He seems disillusioned due to getting older, and often mentions his drinking. Does not speak so easily about health matters; he uses short statements when he replies to my questions.
Paul	61-80	High blood pressure, enlarged prostate, urticaria currently under investigation	1-5	A	a		X	This participant is a very serious person who wants to do the right thing. He seems to like being interviewed, and says he is surprised over how much he had to say.
Joyce	61-80	Osteoarthritis, scoliosis, high blood pressure, breast cancer (past), DVT (past)	>5	A	a		X	She has strong personal views about what is the right thing to do regarding health and medicines, but also says it is an individual decision for people to make. Shares her views, but also lets me know when she has nothing more to say.
Judy	61-80	Slightly elevated BP. Otherwise in good health	1-5	A	a		X	A reflecting, professional person with a background in nursing. She seems to be interested in the questions I ask and really thinks about the answers, giving me her personal and professional view. The interview is split between her account of using medicines and a conversation about balancing personal decisions and official information about health-related behaviour.
Michelle	41-60	Poli arthritis, high blood pressure, depression.	>5	B/C	c		X	A person interested in research! She wants to know how my study will be used and what it can lead to. Tells me straightforwardly why she wanted to participate, and shares a strong story about what medicines can do for you and to you, and how difficult life can be.  <i>(continues overleaf)</i>

Fred	61-80	Heart problems: I had a treble bypass 17 years ago. I have a pace-maker in 6 months ago.	1-5	B	a	X		This man does not worry too much about health, but wants his body to function so he can keep up his daily activities. He seems a little nervous to talk to me, but wants to do a good job with the interview. Gives me vivid descriptions of his heart operations.
James	61-80	I have type 2 diabetes & high blood pressure, also I have had my prostate removed, prostate cancer, back problems. 2 fractures of the spine and a degenerative disc.  Heart problems: N/A. I take tablets for my blood pressure, all under control.	>5	B	b		X	As I step into the house I realise that he has probably recently lost his wife and this catches me a little off guard. He has been her carer for some years and that has had a large impact on his life. This man is an original scouser with strong connections to his family and neighbourhood, and he describes health as entwined with work and responsibilities.
Samuel	61-80	Type 2/depression/loss of memory.	>5	B	c		X	A participant who offers me his own views on the NHS and health policies, in addition to answering my questions. Neither the memory loss nor the depression that he stated in the questionnaire was noticeable. Says he has not discussed his medicines with anyone before this interview.  <i>(continues overleaf)</i>

Stephen	61-80	COPD**, Raynaud's disease, mucous membrane, cervical spondylosis.	>5	B	b		X	This participant expresses his anxiety over ill health and reliance on medicines, and he worries about side effects. He asks for my opinion as a pharmacist, and I have to be upfront with the fact that I can't give advice since I'm not licenced to practice in the UK. Instead, we agree that he can go and talk to his local pharmacist about it.
Tobias	80+	Heart problem since 2003. Anterioseptal myocardial infarction, severe LVSD***, mild to moderate aortic stenosis, dyslipidaemia, CKD3****, macular degeneration.	>5	A	a	X		He starts by explaining how his severe heart condition restricts his mobility – he basically cannot leave Liverpool. Despite this he sees himself as in perfect health and has a serene outlook on life, which he shares with great confidence.

\* not clear whether this means his seventies or the 1970's

\*\* chronic obstructive pulmonary disease

\*\*\* left ventricular systolic dysfunction

\*\*\*\* chronic kidney disease stage 3